

# MONOFEME®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using MONOFEME?

MONOFEME contains the active ingredients ethinylestradiol and levonorgestrel. MONOFEME is used to prevent pregnancy. For more information, see Section [1. Why am I using MONOFEME?](#) in the full CMI.

### 2. What should I know before I use MONOFEME?

Do not use if you have ever had an allergic reaction to ethinylestradiol or levonorgestrel, or any other similar oral contraceptives, or any of the ingredients listed in Section 7. Product Details in the full CMI. Do not use MONOFEME if you have or have had thromboembolism/disease in any blood vessels or liver disease. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MONOFEME?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interact with MONOFEME and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MONOFEME?

Take one tablet at the same time every day, regardless of how often you have sex. It is very important to follow the instructions provided in the full CMI for the medicine to work.

See the full CMI Section [4. How do I use MONOFEME?](#) for instructions on how to start taking MONOFEME for the first time or how to change to MONOFEME from a different contraceptive and other additional instructions.

### 5. What should I know while using MONOFEME?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using MONOFEME.</li><li>• Tell your doctor immediately if you</li></ul>
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	<p>become pregnant while taking MONOFEME.</p> <ul style="list-style-type: none"> <li>• See your doctor if you have not taken your tablets correctly and have missed a period.</li> <li>• Have regular check ups from your doctor, including a Pap smear.</li> <li>• Perform regular breast self-examination</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine or change the dosage, without checking with your doctor.</li> </ul> <p>If you stop taking MONOFEME or do not take a tablet every day without using another form of contraception, you may become pregnant.</p>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Make sure you know how MONOFEME affects you before you drive or use machines.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep MONOFEME in a cool, dry place where the temperature stays below 25°C.</li> </ul>

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack, they may not keep well.

For more information, see Section [5. What should I know while using MONOFEME?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include changes to your bleeding patterns, painful periods, breast tenderness, changes in sex drive, nausea or vomiting, abdominal pain, cramps or bloating, changes to your mood, headaches, weight changes, swelling of the hands, ankles or feet, acne, loss of scalp hair, increase in body hair. More serious side effects include blood clots, worsening or new onset of migraines/headaches, jaundice (yellowing of skin or eyes), significant rise in blood pressure, worsening of existing conditions, e.g. epileptic seizures.

For full list of side effects and further information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# MONOFEME®

**Active ingredient(s):** *ethinylestradiol and levonorgestrel*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using MONOFEME. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MONOFEME.**

**Where to find information in this leaflet:**

- [1. Why am I using MONOFEME?](#)
- [2. What should I know before I use MONOFEME?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MONOFEME?](#)
- [5. What should I know while using MONOFEME?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using MONOFEME?

**MONOFEME contains the active ingredients ethinylestradiol and levonorgestrel.** MONOFEME is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill".

MONOFEME is used to prevent you from becoming pregnant in several ways, if taken correctly:

- By preventing ovulation (the release of an egg from the ovary) during each menstrual cycle.
- It changes the cervical mucus consistency making it difficult for the sperm to reach the egg.
- It changes the lining of the uterus making it less suitable for implantation.

Your doctor may have prescribed MONOFEME for another reason.

Ask your doctor if you have any questions about why MONOFEME has been prescribed for you.

## **2. What should I know before I use MONOFEME?**

### **Warnings**

#### **Do not use MONOFEME if:**

1. You are allergic to ethinylestradiol or levonorgestrel, or any other similar medicines (such as other oral contraceptives) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing

- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

**Always check the ingredients to make sure you can use this medicine.**

2. You have, or have had any of the following medical conditions:

- Venous thromboembolism (VTE) and are on medicines called anticoagulants which are used to "thin the blood"
- Hereditary or acquired disposition of VTE
- Multiple risk factors for VTE including obesity, age above 35 years, smoking, high cholesterol
- Blood clots or a history of blood clots in legs (deep vein thrombosis (DVT)), or lungs (pulmonary embolism (PE)) or eyes and you are currently taking an anticoagulant medicine
- Major surgery and have been confined to bed for long periods of time
- Arterial thromboembolism (ATE) or past history of these that include:
  - Stroke
  - Angina
  - Transient ischaemic attack or "mini stroke"
- Hereditary or acquired disposition for ATE
- History of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound, or noise
- Multiple risk factors for ATE or a serious risk factor for ATE that include:

- Uncontrolled high blood pressure
  - Diabetes with blood vessel damage
  - Severe lipid disease (high levels of fatty substances in the blood)
  - Sickle cell anaemia
  - Disease in any blood vessel(s)
  - Inflammation of the pancreas which is associated with very high blood levels of triglycerides (fatty substances).
  - Liver disease (including tumours of any type), yellowing of the whites of the eyes or of the skin (jaundice) or a history of jaundice or cholestatic jaundice of pregnancy, or severe generalised itch in the body during pregnancy, Dubin-Johnson Syndrome or Rotor Syndrome.
  - Unexplained vaginal bleeding
  - Cancer or suspected cancer of the breast or sex organs (e.g. cervix, vagina, ovaries, endometrium, womb) and known or suspected estrogen-dependent tumours.
  - A family history of breast nodules, fibrocystic disease or have had an abnormal mammograph.
3. You are pregnant or you think you are pregnant. Pregnancy must be excluded before you start taking MONOFEME.
4. You are taking anti-viral hepatitis C virus (HCV) medicinal products such as those containing ombitasvir, paritaprevir, ritonavir and dasabuvir with or without ribavirin.



If you are not sure about your anti-HCV medication, tell your doctor.

5. You have already experienced menopause.

If you are not certain whether these may apply to you, or you are worried by anything in this list, tell your doctor.

## **Medical Check-ups**

- Before you start to take MONOFEME, you must have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine test.

## **Check with your doctor if you:**

- Take any medicines for any other condition
- Have any other medical conditions or health problems, such as:
  - Heart disease including heart valve disorders or certain heart rhythm disorders
  - High blood pressure, a history of high blood pressure or high blood pressure during pregnancy
  - High cholesterol
  - Hepatitis C
  - Diabetes
  - Migraine or other headaches
  - Hyperhomocysteinemia
  - Breast lumps, abnormal breast X-ray or mammogram
  - Gallbladder disease
  - Fluid retention or kidney disease

- Yellowing of the whites of the eyes or skin (jaundice) during pregnancy or during previous oral contraceptive use
- Multiple sclerosis
- Epilepsy
- Depression
- Asthma
- Fibroids
- Hereditary angioedema (swelling of the face, lips, mouth, tongue or throat).

If you have any of these conditions, you should have regular check-ups with your doctor to make sure that taking MONOFEME is not making the conditions worse.

- Are older than 35 years of age or are overweight.
- Are intolerant to some sugars, or your doctor has told you so. MONOFEME contains lactose.
- Are allergic to any foods, dyes, preservatives or any other medicines.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

- Check with your doctor if you are pregnant or intend to become pregnant.
- Your doctor will advise you how to take MONOFEME after a miscarriage or abortion.

- If you have just had a baby, talk to your doctor before you start taking MONOFEME.
- Talk to your doctor if you are breastfeeding or intend to breastfeed.
- Your doctor can discuss the risks and benefits involved with you.

## **Blood clots**

- You must tell your doctor if you or anyone in your immediate family has or has had blood clots in the legs or lungs.
- Blood clots are a rare occurrence when taking an oral contraceptive.
- The risk of a blood clot is highest during the first year of taking an oral contraceptive for the first time or if you are re-starting the "pill" after a break of 4 weeks or more.
- The risk of having a blood clot is higher in oral contraceptive users than in non-users but is not as high as during pregnancy.

**Tell your doctor about any of the following conditions as these are risk factors for developing blood clots:**

- Cancer
- Systemic lupus erythematosus (SLE)
- Haemolytic uraemic syndrome (HUS) - a disorder of blood coagulation causing failure of the kidneys)
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)

- Sickle cell disease
- Smoking particularly if you are heavy smoker (15 or more cigarettes per day) and are aged over 35 years
- Have had any recent surgery or trauma
- Recently had a baby
- Lost a baby in the second trimester
- Are pregnant
- Had major surgery and have been confined to bed for long periods of time
- Also tell your doctor if you are planning a long haul plane flight (greater than 4 hours).

## **Stroke**

- You must tell your doctor if you or anyone in your immediate family has or has had a stroke or heart attack.
- Taking oral contraceptives is linked with an increased risk of having a heart attack, angina, stroke or a "mini stroke".

**If you have not told your doctor about any of the above, tell him/her before you start taking MONOFEME.**

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including all prescription medicines and any medicines, vitamins or supplements that you buy without

a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interact with MONOFEME and affect how well it or the other medicine works. This may lead to unwanted side effects, reduce the effect of MONOFEME and/or the other medicine.**

**These medicines include:**

- Atorvastatin used to treat high cholesterol
- Indinavir for the treatment of HIV infection
- Anti-fungal medicines such as itraconazole and fluconazole
- Paracetamol
- Ascorbic acid (Vitamin C)
- Cyclosporin used to prevent organ rejection
- Theophyllines used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine for seizures.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MONOFEME.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

**Medicines that may reduce the effect of MONOFEME include:**

- Anti-viral hepatitis C virus (HCV) medicines such as ombitasvir, paritaprevir, ritonavir and dasabuvir

- Rifampicin and rifabutin for the treatment of infections such as tuberculosis
- Antibiotics such as ampicillin, other penicillins and tetracyclines
- Anti-fungal agents such as griseofulvin
- Barbiturates (medicines prescribed for epilepsy, such as phenobarbital)
- Medicines for epilepsy such as phenytoin, primidone, carbamazepine and topiramate
- Ritonavir for the treatment of HIV infection
- Modafinil used to treat excessive daytime sleepiness
- Corticosteroids such as dexamethasone
- St John's wort, an ingredient found in medicines you can purchase without a prescription from a pharmacy, supermarket or health food shop
- Corticosteroids such as dexamethasone.

**While you are taking these medicines, and for seven days after stopping them, you must use a non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods).**

**If the seven days extend into the inactive red tablet section, then you should start a new pack on the next day after having taken the last white active tablet from the current pack. Skip the 7 red tablets.**

This is particularly important if you need to take antibiotics or medicines for epilepsy.

If you take rifampicin and some other medicines, you may need to use additional non-hormonal contraception for four weeks after finishing the course of treatment.

Ask your doctor or pharmacist about how long you need to use additional non-hormonal contraception.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MONOFEME.**

## **4. How do I use MONOFEME?**

**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### **How much to take**

- Take one tablet every day.
- Follow the instructions provided and use MONOFEME until your doctor tells you to stop.

### **When to take MONOFEME**

- MONOFEME should be taken at the same time every day regardless of how often you have sex.
- MONOFEME will work best if you do not miss any tablets and take it at the same time each day. Taking MONOFEME at the same time each day will also help you remember when to take your tablets.

- It does not matter if you take MONOFEME before or after food.
- If you are concerned about this, please speak to your doctor or pharmacist.

## **How to take MONOFEME**

- Swallow the tablet whole with a full glass of water.

## **How long to take it**

Continue taking your medicine for as long as your doctor tells you. Your doctor may prescribe MONOFEME for long periods, until you no longer need or want contraception.

**If you are not sure how long you should be taking MONOFEME, ask your doctor.**

## **How to start taking hormonal contraceptive for the first time**

- To begin MONOFEME, take your first white tablet on the first day of your next period, that is, the day your bleeding starts.
- Take a white tablet that matches the day of the week from the green shaded section of the blister pack. For example if your period commences on a Friday, then take a white tablet marked Friday.

**You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature**



**methods) until a white tablet has been taken daily for 7 days without a break.**

- Continue to take one white tablet every day, following the arrows around the strip, until you finish all 21 white tablets.
- Then take one red tablet daily for the next 7 days, following the arrows so that you are taking the correct tablet for the day of the week. Taking these red tablets helps you to remember to take a tablet every day.
- You can expect your period during the week that you are taking these red inactive tablets. Your protection continues during this week.

**If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all the instructions in this leaflet, contact your doctor to check if you are pregnant.**

## **Going on to further blister packs**

- On the day after your last red tablet, begin the next pack with a white tablet from the green shaded section of the blister pack that matches the day of the week. Do this even if you are still bleeding.
- Each new pack is started with a white tablet on the same day as the first pack, so that you have 21 days on white tablets, then 7 days on red tablets. There is no break between packs.
- **If you start taking your new pack late, you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until**

**a white tablet has been taken daily for 7 days without a break.**

## **Switching to MONOFEME from a different combined oral contraceptive**

**When changing from a different combined oral contraceptive to MONOFEME, it is important to follow the instructions below carefully.**

MONOFEME works best if you do not miss any tablets and take it at the same time each day.

**Follow these steps if your current oral contraceptive contains an estrogen and a progestogen:**

- Stop taking your current oral contraceptive after you have taken the last active tablet in the strip. If your current oral contraceptive pack also contains inactive or reminder tablets, do not take them.
- Start the new MONOFEME pack on the next day by taking a white active tablet from the top row which corresponds to the day of the week.

**You must use an additional, non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.**

- Continue to take one white tablet every day, following the arrows around the strip until you finish all 21 white tablets in the green shaded section of the strip.
- Then take one red tablet daily for the next 7 days, before starting your new strip.

- You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

**If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all the instructions in this leaflet, contact your doctor to check if you are pregnant.**

### **Switching from a progestogen-only contraceptive:**

You can stop taking a progestogen-only contraceptive tablet any day and start taking MONOFEME the next day, at the same time.

If you have been using a progestogen implant, start taking MONOFEME on the day the implant is removed.

If you have been using a progestogen injection, start taking MONOFEME when your next injection would be due.

In all cases start MONOFEME by taking a white tablet from the green shaded section that matches the day of the week.

**You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.**

## **If you forget to use MONOFEME**

MONOFEME should be used regularly at the same time each day. If you miss your dose at the usual time, it may not work as well in protecting you from becoming pregnant.

**Do not take a double dose to make up for the dose you missed.**

### **If you miss a white active tablet:**

- If you are less than 12 hours late in taking your tablet, you should take that tablet immediately and then take the next one at your usual time, even if this means taking two tablets in one day.
- If you are more than 12 hours late in taking your tablet or if two active white tablets are missed, MONOFEME may not work as well in protecting you from becoming pregnant. You should take the missed tablet immediately and then take the next one at your usual time, even if this means taking two tablets in one day.
- **Continue to take tablets at the usual time and use an additional, non-hormonal method of contraception for the next seven days (such as condoms or a diaphragm, but not the rhythm or temperature methods).** If you come to the end of the white tablets during the 7 days after a missed tablet, start the next pack straight away. Skip the 7 red tablets.

**If you miss three or more white tablets, contact your doctor for advice on what to do.**

**If you miss a red inactive tablet, leave them in the pack and do not worry. Additional birth control method is not necessary in this case.**

**However, if you miss red tablets and then forget to start the next pack on time, start as soon as you remember by taking a white tablet that matches the day of the week from the green shaded section. You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.**

If your doctor told you to take MONOFEME differently, or you are unclear about the above directions, discuss this with them.

If you have trouble remembering to take MONOFEME, ask your pharmacist for some hints.

## **If you vomit or have diarrhoea while taking MONOFEME**

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of MONOFEME may be reduced. The white tablets may not have time to be absorbed properly and may not protect you from becoming pregnant. If vomiting or diarrhoea occurs within 4 hours after taking a pink tablet, you must take an extra pink tablet from a back-up pack.

During any period of vomiting or diarrhoea, continue taking MONOFEME tablets. Also use a non-hormonal method of contraception (such as condoms or a

diaphragm, but not the rhythm or temperature methods), and continue for seven days following the episode of vomiting or diarrhoea. If these seven days extend into the inactive red tablet section, you should start a new pack on the next day after having taken the last active white tablet from the current pack (i.e. skip the 7 red inactive tablets).

You may not have a period until you finish the second pack.

If you have vomiting or diarrhoea after taking a red tablet, do not worry.

## **If you take too much MONOFEME**

If you think that you have taken too much MONOFEME, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include:

- Feeling sick or vomiting,
- Dizziness
- Feeling sleepy or tired
- Women may also experience menstrual bleeding.

Serious ill effects have not been reported in young children who have taken large doses of birth control pills.

## **5. What should I know while using MONOFEME?**

### **Things you should do**

- Tell all doctors, dentists and pharmacists who are treating you that you are taking MONOFEME.
- Tell the hospital doctor that you are taking MONOFEME birth control pills if you need to have an operation or go to hospital in an emergency.
- If you are about to be started on any new medicine, tell your doctor or dentist and your pharmacist that you are taking MONOFEME.
- If you become pregnant while taking MONOFEME, see your doctor immediately.
- If you are about to have any blood tests, tell your doctor you are taking MONOFEME. It may interfere with the results of some tests.
- Tell your doctor you are taking MONOFEME at least 4 weeks before any planned hospitalisation or surgery. Your doctor may tell you to stop taking MONOFEME several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking MONOFEME after you are back on your feet.

To avoid pregnancy during this time you must use a non-hormonal method of contraception such as condoms or a diaphragm.

## **Missed periods**

- If you miss a period and you have taken your tablets correctly, continue taking your tablets as you would normally.

Sometimes you might not have a menstrual period while taking MONOFEME.

- If you miss a period and you have not taken your tablets correctly, keep taking your tablets and see your doctor immediately.

Not taking your tablets correctly includes missing one or more tablets or starting a new pack later than you should have.

- If you miss two menstrual periods, stop taking your tablets and see your doctor, even if you have taken the tablets correctly. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) during this time.

Your doctor should make sure you are not pregnant before you start taking MONOFEME again.

## **Medical Check Up**

- Visit your doctor regularly for check-ups and physical examinations, including Pap smears, blood pressure checks and breast, abdomen and pelvic organ examinations. Oral contraceptives should not be



prescribed for longer than one year without your doctor carrying out a check-up.

- A pap smear can detect any abnormal cells from the cervix, which may develop into cancer. Cervical cancer has been reported to occur more frequently in women who use oral contraceptives for a long time.
- Your doctor will advise you of the type and frequency of any tests required.

## **Breast cancer risk**

- Perform regular breast self-examination
- Examining your breasts for lumps or any changes in size or shape can help you find a breast cancer early. Breast cancer has been found slightly more frequently in women who use oral contraceptives. It is not known whether this increase is caused by the use of oral contraceptives, or if it is due to the fact that users were examined more often, and therefore the breast cancer was detected earlier.
- If you are unsure, ask your doctor about breast self-examination.

## **Sexually transmitted disease (STD)**

- If you are worried about contracting a sexually transmitted disease (STD) use a barrier contraceptive method such as a condom.
- MONOFEME does not protect against the transmission of STDs such as HIV-AIDS, chlamydia, genital herpes and warts, gonorrhoea, hepatitis B, human papilloma virus or syphilis. To protect against

STDs ask your partner to wear a condom when having sexual intercourse with you.

## **Things you should not do**

- Do not take MONOFEME if the packaging is torn or shows signs of tampering.
- If it is expired or is damaged, return it to your pharmacist for disposal.

MONOFEME may have no effect at all, or worse, have an entirely unexpected effect, if you take it after the expiry date.

- Do not take MONOFEME to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else even if they have the same condition as you.
- Do not stop taking MONOFEME, or change the dosage, without checking with your doctor.
- If you stop taking MONOFEME or do not take a tablet every day, without using another form of contraception, you may become pregnant.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how MONOFEME affects you.**

MONOFEME is not expected to affect your ability to drive a car or operate machinery.

## **Drinking alcohol**

No information available.

## **Looking after your medicine**

- Keep your MONOFEME tablets in a dry place, at a temperature below 25°C.
- Do not keep your tablets in the refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

### **Keep it where young children cannot reach it.**

- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **After stopping MONOFEME**

**If your periods do not return within 2 to 3 months of stopping MONOFEME tell your doctor.**

Delays in becoming pregnant may occur after MONOFEME therapy is stopped. This is more likely to occur in women whose periods were irregular before using birth control pills.

**If you are planning to become pregnant after stopping MONOFEME, use a non-hormonal method of contraception such as condoms or a diaphragm for 3 months before trying to get pregnant.** Ask your doctor or pharmacist for advice about taking folic acid if you plan to become pregnant.

See your doctor if you continue to experience difficulties in falling pregnant.

## **When to discard your medicine**

If your doctor tells you to stop taking MONOFEME or if the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Side effects

Side effects	What to do
<p data-bbox="204 432 735 533"><b>Reproductive or breast problems:</b></p> <ul data-bbox="204 568 767 1951" style="list-style-type: none"><li data-bbox="204 568 767 792">● changes in bleeding patterns, including break-through bleeding/spotting</li><li data-bbox="204 808 564 860">● painful periods</li><li data-bbox="204 875 735 1211">● missed periods, but if you have not taken MONOFEME as directed you should check whether you are pregnant</li><li data-bbox="204 1227 687 1330">● change in menstrual flow</li><li data-bbox="204 1346 751 1518">● change in cervical secretions (mucus from the vagina)</li><li data-bbox="204 1534 639 1704">● vaginal thrush (Candida), vaginal irritation</li><li data-bbox="204 1720 767 1890">● breast pain, tenderness, enlargement, possible milk secretion</li><li data-bbox="204 1906 730 1951">● change in sexual drive</li></ul>	<p data-bbox="810 432 1337 651"><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Side effects</b>	<b>What to do</b>
<p><b>Stomach problems such as:</b></p> <ul style="list-style-type: none"> <li>● gastric or stomach discomforts including abdominal pain, cramps, bloating, nausea, vomiting and diarrhoea</li> <li>● change in appetite.</li> </ul> <p><b>Difficulties thinking or working because:</b></p> <ul style="list-style-type: none"> <li>● headache, including migraines</li> <li>● nervousness, dizziness</li> <li>● mood change, including depression</li> <li>● contact lenses becoming uncomfortable to wear</li> </ul> <p><b>Changes to your appearance such as:</b></p> <ul style="list-style-type: none"> <li>● change in weight</li> <li>● swelling of the hands, ankles or feet</li> <li>● dark discolouration of the skin (which may persist after the tablets have been stopped)</li> <li>● loss of scalp hair</li> </ul>	

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• increase in body hair</li> <li>• acne, rashes</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Worsening of your existing conditions such as:</b></p> <ul style="list-style-type: none"> <li>• chorea (involuntary muscle spasm)</li> <li>• porphyria (a group of disorders than can cause skin or nerve problems)</li> <li>• systemic lupus erythematosus (Lupus)</li> <li>• varicose veins</li> <li>• gallbladder disease</li> <li>• kidney disease</li> <li>• hereditary angioedema (swelling of the face lips, mouth tongue or throat)</li> <li>• You are an epileptic and your fits become more frequent</li> </ul> <p><b>Pain or discomfort:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p>You may need urgent medical attention or hospitalisation.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● fever</li> <li>● unexplained or persistent pains in the head, chest, arm or below the breastbone</li> <li>● severe pain, swelling or discolouration in either of your legs</li> <li>● discomfort radiating to the back, jaw, throat or stomach</li> <li>● abdominal pain</li> <li>● weakness or numbness in any part of your body</li> </ul> <p><b>Digestive system problems:</b></p> <ul style="list-style-type: none"> <li>● bloody diarrhoea</li> <li>● feeling of indigestion or choking</li> <li>● rectal bleeding</li> <li>● loss of appetite or weight loss</li> </ul> <p><b>Problems with your eyes or eyesight:</b></p> <ul style="list-style-type: none"> <li>● blurred or double vision</li> <li>● partial or complete loss of sight</li> </ul>	



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● eye protrusion, swelling of the eye or eye lesions</li> </ul> <p><b>Migraines:</b></p> <ul style="list-style-type: none"> <li>● migraine headaches for the first time</li> <li>● more frequent or severe migraines if you already suffer from them</li> </ul> <p><b>General feelings of unwellness, including:</b></p> <ul style="list-style-type: none"> <li>● feeling tired</li> <li>● shortness of breath</li> <li>● rapid or irregular heartbeat</li> <li>● dizziness or fainting, sometimes with loss of balance</li> <li>● sweating, nausea or vomiting</li> <li>● an unusual cough</li> </ul> <p><b>Changes to your body:</b></p> <ul style="list-style-type: none"> <li>● confusion, trouble speaking or understanding</li> <li>● breast lumps</li> <li>● jaundice or a yellowing of the skin or eyes,</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>often with fever, fatigue, loss of appetite, dark coloured urine, nausea and vomiting. Taking oral contraceptives may be associated with liver disease including liver cancer</p> <ul style="list-style-type: none"> <li>● itchy rash</li> <li>● rise in blood pressure. You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any of these symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked.</li> <li>● swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MONOFEME contains

<b>Active ingredient (main ingredient)</b>	Each white active tablet contains: <ul style="list-style-type: none"><li>• levonorgestrel 100 micrograms (mcg)</li><li>• ethinylestradiol 20 micrograms (mcg)</li></ul> The red tablets do not contain active ingredients.
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<p><b>Other ingredients (inactive ingredients)</b></p>	<p>The white active tablets also contain:</p> <ul style="list-style-type: none"><li>● Lactose monohydrate</li><li>● Maize starch</li><li>● Povidone</li><li>● Purified talc</li><li>● Magnesium stearate</li><li>● Sucrose</li><li>● Macrogol 6000</li><li>● Calcium carbonate</li><li>● White beeswax</li><li>● Carnauba wax</li></ul> <p>The red inactive tablets contain:</p> <ul style="list-style-type: none"><li>● Lactose monohydrate</li><li>● Maize starch</li><li>● Povidone</li><li>● Purified talc</li><li>● Magnesium stearate</li><li>● Sucrose</li><li>● Macrogol 6000</li><li>● Calcium carbonate</li><li>● Glycol montanite</li><li>● Brilliant scarlet 4R</li><li>● Erythrosine</li></ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

**MONOFEME contains lactose.**

**MONOFEME does not contain gluten, tartrazine or any other azo dyes.**

## **What MONOFEME looks like**

MONOFEME is available in a 16-week box containing 4 blister packs. Each blister pack contains 21 white hormone tablets and 7 red nonhormonal tablets. The blister pack is marked with days of the week next to each tablet.

(AUST R 296399)

## **Who distributes MONOFEME**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

This leaflet was prepared in July 2025.