STAMARIL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor or pharmacist.

1. Why am I or my child receiving Stamaril?

Stamaril contains the active ingredient attenuated (weakened) yellow fever virus. Stamaril is a vaccine that provides protection against the serious infectious disease, yellow fever. Yellow fever occurs in certain areas of the world and is spread to people through the bites of infected mosquitoes.

For more information, see Section 1. Why am I or my child receiving Stamaril? in the full CMI.

2. What should I know before my child or I receive Stamaril?

Do not use if you or your child have ever had a severe allergic reaction to Stamaril or a similar vaccine, the active ingredient, eggs, chicken proteins, or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you or your child 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 my child or I receive Stamaril? In the full CMI.

3. What if I or my child is taking other medicines?

Some medicines may interfere with Stamaril and affect how it works.

A list of these medicines is in Section 3. What if I or my child is taking other medicines? in the full CMI.

4. How is Stamaril given?

- Stamaril is given as a 0.5mL injection, usually under the skin but can be given into a muscle by a doctor or nurse.
- The injection should be given at least 10 days before being at risk of infection with yellow fever.

More instructions can be found in Section 4. How is Stamaril given? in the full CMI.

5. What should I know while being given Stamaril?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are receiving Stamaril. • Tell your doctor or nurse if you are pregnant, think you might be pregnant, or are breastfeeding. You should not receive Stamaril if you are pregnant or breastfeeding. • If you need to receive Stamaril but are breastfeeding, you will need to stop breastfeeding for at least two weeks after receiving Stamaril. • Tell your doctor or nurse if you are feeling unwell after receiving Stamaril.
Looking after your medicine	Stamaril is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Stamaril: • Keep Stamaril in the original pack until it is time for it to be given. • Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Stamaril. Protect from light.

For more information, see Section 5. What should I know while being given Stamaril? in the full CMI.

6. Are there any side effects?

The most common side effects of Stamaril are injection site redness, pain or discomfort, unusual weakness, muscle tenderness or weakness not caused by exercise, headaches, fever, crying and irritability in children, painful joints, rash, feeling sick, vomiting or stomach pain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

STAMARIL®

Active ingredient: yellow fever virus (live, attenuated)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I or my child receiving Stamaril?
2. What should I know before my child or I receive Stamaril?
3. What if I or my child is taking other medicines?
4. How is Stamaril given?
5. What should I know while being given Stamaril?
6. Are there any side effects?
7. Product details

1. Why am I or my child receiving Stamaril?

Stamaril contains the active ingredient attenuated (weakened) yellow fever virus. Stamaril is a vaccine that provides protection against a serious infectious disease called yellow fever.

Yellow fever occurs in certain areas of the world and is spread to people through the bites of infected mosquitoes.

Stamaril is given to people who:

1) are travelling to, passing through or living in an area where yellow fever is present or may be present.

2) are travelling to any country that requires an International Certificate of Vaccination for entry, this may depend on the countries previously visited during the same trip.

3) may handle infectious materials such as laboratory workers.

To obtain a vaccination certificate against yellow fever it is necessary to be vaccinated in an approved vaccination centre by a qualified and trained health care professional so that an International Certificate of Vaccination can be issued. This certificate is valid from the 10th day after the vaccination.

2. What should I know before my child or I receive Stamaril?

Warnings

Stamaril must not be given to:

- women who are pregnant or breast-feeding,
- children under 6 months of age.

Stamaril should not be given if you or your child:

- have ever had a severe allergic reaction to the active ingredient, eggs, chicken proteins or any other ingredient of Stamaril,
- have experienced a severe allergic reaction after an injection of a yellow fever vaccine,
- have an illness with a fever or acute infection. The vaccination will be postponed until you have recovered,
- have a poor or weakened immune system for any reason, such as illness or medical treatments (for example corticosteroids or chemotherapy),
- have a weakened immune system due to HIV infection. Your doctor will tell you if you can still receive Stamaril based on your blood tests,
- are infected with HIV and have active symptoms due to the infection,
- have a history of problems with thymus gland or has had thymus gland removed for any reason.

Always check the ingredients to make sure you can be given this vaccine.

Check with your doctor if:

- you are taking any medicines for any other condition,
- you are over 60 years old as you have an increased risk of certain types of severe but rare reactions to vaccines (including serious reactions that affect the brain and nerves, as well as vital organs). You will only be given the vaccine if the risk of infection with the virus is well established in countries where you are going to stay,
- your child is aged 6 to 9 months. Stamaril may be given to children aged between 6 and 9 months only in special situations and on the basis of current official recommendations,
- you are infected with the HIV but do not present with any HIV infection related symptoms, your doctor will specify whether Stamaril can be given based on your blood tests,
- your child is infected with the HIV (AIDS). The doctor may need to perform specific exams and seek advice from a specialist before telling you whether your child may receive Stamaril,
- you have bleeding disorders (such as haemophilia or a low level of platelets) or are taking medicines that reduce blood circulation. You can still receive Stamaril provided that it is injected under the skin and not into a muscle,
- you or your child have rare hereditary problems of fructose intolerance. Stamaril contains a small amount of sorbitol and should not be given to people who have fructose intolerance.

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

Tell your doctor or nurse if you are pregnant, think you might be pregnant or are breastfeeding. You should not receive Stamaril unless this cannot be avoided.

If Stamaril is needed, you will need to stop breastfeeding for at least 2 weeks after receiving Stamaril.

Your doctor or nurse can advise you on whether it is essential that you receive Stamaril while pregnant or breastfeeding.

3. What if I or my child is taking other medicines?

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have recently been receiving any treatment which may have weakened your immune system (such as chemotherapy or high doses of corticosteroids), vaccination against yellow fever should be postponed until your laboratory results show that your immune system has recovered. Your doctor will advise you when it is safe for you to be vaccinated.

Stamaril can be given at the same time as vaccines against typhoid (those containing the Vi capsular polysaccharide).

In adults, Stamaril can be given at the same time as IMOJEV (live attenuated vaccine against Japanese encephalitis).

Your doctor will advise you if Stamaril can be given with another vaccine.

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

4. How is Stamaril given?

How much is given

- Stamaril is given as a single 0.5mL dose by your doctor or nurse.
- Stamaril is given as an injection, usually under the skin, but it can be given into a muscle. It must not be injected into a blood vessel.

When Stamaril is given

- The injection should be given at least 10 days before being at risk of infection with yellow fever, because it takes 10 days for the vaccine to work and provide good protection against the yellow fever virus.
- The protection will last at least 10 years and may be a life-long protection. Some people may need to be re-vaccinated if they continue to be at risk for yellow fever virus infection.

If you are given too much Stamaril

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

5. What should I know while being given Stamaril?

Call your doctor straight away if you:

- Do not feel well after receiving Stamaril

Remind any doctor, dentist or pharmacist you visit that you have received Stamaril.

Looking after your medicine

Stamaril is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Stamaril:

- Keep Stamaril in the original pack until it is time for it to be given.
- Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze Stamaril. Protect from light.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this vaccine after the expiry date.

6. Are there any side effects?

All vaccines 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.

Less serious side effects

Less serious side effects	What to do
Body as a whole • Feeling sick. • Fever, crying, irritability, drowsiness, vomiting, or appetite loss in children. • Flu-like symptoms, such as high temperature, sore throat, runny or blocked nose, sneezing, cough and chills. • Facial pressure and pain. • Temporary lack of white blood cells, symptoms for which include frequent infections such as fever, severe chills, sore throat or mouth ulcers.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Swollen glands in the neck, armpit or groin. • Fever. **Brain and nervous system** • Headaches. • Dizziness or fainting. • Tingling or numbness of the hands or feet. **Gastrointestinal** • Vomiting. • Stomach pain. • Diarrhoea. **Injection site-related** • Injection site pain or discomfort. • Redness, swelling, bruising or appearance of a hard lump. **Muscles, joints and connective tissue** • Painful joints. • Unusual weakness. • Muscle tenderness or weakness not caused by exercise. **Skin** • Rash or itchiness.	

Serious side effects

Serious side effects	What to do
Allergic reaction • Rash, itching or hives on the skin. • Swelling of the face, lips, tongue or other parts of the body. • Difficulty swallowing or breathing. • Loss of consciousness. **Brain and nervous system** These may occur within one month of the vaccination and have sometimes been fatal: • High fever with headache and confusion. • Extreme tiredness. • Personality change. • Stiff neck.	**Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• Inflammation of brain and nerve tissues. • Fits. • Loss of movement or feeling affecting certain parts or all of the body. **Vital organs** These may occur within 10 days of the vaccination and may have a fatal outcome. The reaction can resemble an infection with the yellow fever virus. Early symptoms: • Fever, feeling very tired, headache • Muscle pain • Low blood pressure. Later symptoms: • Severe muscle and liver disorders. • Drops in number of some types of blood cells (identifiable through unusual bruising or bleeding or increased risk of infections). • Loss of normal functioning of the kidneys and lungs.	

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 in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/.

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 vaccine is only available with a doctor's prescription.

What Stamaril contains

Active ingredient (main ingredient)	Yellow fever virus (produced in specified pathogen-free chick embryos), 17D strain (live,

	attenuated): not less than 1000 IU
Other ingredients (inactive ingredients)	Histidine hydrochloride, alanine, sodium chloride, potassium chloride, sodium phosphate dihydrate, monobasic potassium phosphate, calcium chloride dihydrate, magnesium sulfate heptahydrate and water for injections.
Potential allergens	Sorbitol Lactose monohydrate

Do not receive this vaccine if you are allergic to any of these ingredients.

The manufacture of this vaccine includes exposure to bovine materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

What Stamaril looks like

Stamaril is a beige to orange beige homogenous powder, which after reconstitution with sodium chloride solution (a clear and colourless solution) forms a beige to pinked beige suspension, which is more or less opalescent.

AUST R 58571

Who distributes Stamaril

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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