SOTYKTU™

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using SOTYKTU?

SOTYKTU contains the active ingredient deucravacitinib.

SOTYKTU is used to treat adults with moderate to severe plaque psoriasis and psoriatic arthritis. For more information, see Section 1. Why am I using SOTYKTU? in the full CMI.

2. What should I know before I use SOTYKTU?

Do not use if you have ever had an allergic reaction to deucravacitinib or any of the ingredients listed at the end of the CMI.

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 SOTYKTU? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOTYKTU. See Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use SOTYKTU?

- The recommended dose of SOTYKTU is one 6 mg tablet taken by mouth once a day.
- Swallow the tablet whole. Do not crush, cut or chew the tablet.
- It does not matter if you take this medicine before or after food.

More instructions can be found in Section 4. How do I use SOTYKTU? in the full CMI.

5. What should I know while using SOTYKTU?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using SOTYKTU. • Tell your doctor if you currently have an infection that does not go away or that keeps coming back
Things you should not do	• Do not stop taking SOTYKTU without talking to your doctor first.
Driving or using machine	• Be careful before you drive or use any machines or tools until you know how SOTYKTU affects you. • This medicine is not likely to affect you being able to drive, cycle or use any tools or machines.
Looking after your medicine	• Store below 30°C

For more information, see Section 5. What should I know while using SOTYKTU? in the full CMI.

6. Are there any side effects?

Common side effects include a cold, sore throat, runny or blocked nose, cough, sores in the mouth, cold sore blisters, acne-like rash and inflammation of hair follicles. Serious infections with fever, flu-like symptoms, tiredness, shortness of breath or cough which will not go away may need medical attention.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SOTYKTU™ (soh-tik-too)

Active ingredient: deucravacitinib (due-krav-a-sye-ti-nib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOTYKTU. **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 SOTYKTU.**

Where to find information in this leaflet:

1. Why am I using SOTYKTU?
2. What should I know before I use SOTYKTU?
3. What if I am taking other medicines?
4. How do I take SOTYKTU?
5. What should I know while using SOTYKTU?
6. Are there any side effects?
7. Product details

1. Why am I using SOTYKTU?

SOTYKTU contains the active ingredient deucravacitinib.

SOTYKTU is used to treat:

- **adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin, which can cause red, scaly, thick, itchy, painful patches on your skin and can also affect other areas of your body such as scalp, nails, hands, and feet.**
- **adults with active psoriatic arthritis, a disease that causes inflamed joints, and is often associated with plaque psoriasis.**

It works by selectively blocking the activity of an enzyme called tyrosine kinase 2 (TYK2) which is involved in the process of inflammation. By reducing the activity of this enzyme, SOTYKTU can help to control the inflammation associated with psoriasis and psoriatic arthritis, thereby reducing the signs and symptoms of these conditions.

2. What should I know before I use SOTYKTU?

Warnings

Do not use SOTYKTU if:

- you are allergic to deucravacitinib, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- currently have an infection that does not go away or that keeps coming back. SOTYKTU may lower the ability of your immune system to fight infections and may increase your risk of infections.
- have or had hepatitis B or C
- have or had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Your doctor may test you for tuberculosis before starting SOTYKTU.
- have cancer, because your doctor will have to decide if you can still be given SOTYKTU
- recently had or plan to have a vaccination
- have problems with your liver
- have any other medical conditions
- take any medicines for any other condition

Tell your doctor if you have unexplained muscle pain, tenderness or weakness, particularly if you have general body discomfort or fever.

Your doctor may take blood tests before you start treatment with SOTYKTU and while you are taking it. Depending on the results of your blood tests your doctor may suspend or discontinue treatment or prescribe you additional 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

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. This is because it is not known how this medicine will affect the baby.

Small amounts of SOTYKTU pass into your breastmilk. It is not known if SOTYKTU will affect your baby. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children or adolescents

- This medicine is not recommended for use in children and adolescents under 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist:

- if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.
- if you have recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using SOTYKTU.

4. How do I take SOTYKTU?

How much to take

- The recommended dose of SOTYKTU is one 6 mg tablet taken by mouth once a day.
- Swallow the tablet whole. Do not crush, cut or chew the tablet.
- It does not matter if you take this medicine before or after food.
- Follow the instructions provided and use SOTYKTU until your doctor tells you to stop.

SOTYKTU comes in a calendar pack with the days of the week marked on it to help you remember to take your medicine each day. All of the tablets in the pack are the same.

If you forget to use SOTYKTU

SOTYKTU should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much SOTYKTU

If you think that you have used too much SOTYKTU, 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.

5. What should I know while using SOTYKTU?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with SOTYKTU.
- Tell your doctor immediately if you become pregnant while being treated with SOTYKTU

Call your doctor straight away if you:

- experience 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. These could be symptoms of serious allergic reaction.
- currently have an infection that does not go away or that keeps coming back.
- develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats).

Remind any doctor, dentist or pharmacist you visit that you are using SOTYKTU.

Things you should not do

- Do not stop taking SOTYKTU without talking to your doctor first.

Driving or using machines

This medicine is not likely to affect you being able to drive, cycle or use any tools or machines.

Looking after your medicine

- Store below 30°C

Follow the instructions on 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.

Keep it where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

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.

Serious side effects

Serious side effects	What to do
Signs of a serious infection, such as • fever, flu-like symptoms • feeling tired or short of breath, cough which will not go away	**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.**

Other side effects

Very common side effects	What to do
• upper respiratory tract infections with symptoms such as sore throat and stuffy nose	**Speak to your doctor if you have any of these side effects and they worry you.**
Common side effects	
• viral infection of the mouth • sores in the mouth • cold sore blisters • acne-like rashes • inflammation of hair follicles	
Uncommon side effects	
• shingles (herpes zoster)	

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. 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 SOTYKTU contains

Active ingredient (main ingredient)	deucravacitinib
Other ingredients (inactive ingredients)	hypromellose acetate succinate, lactose, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate Film coating: Opadry II Complete Film Coating System 85F140184 Pink (PI 141510)

Do not take this medicine if you are allergic to any of these ingredients.

What SOTYKTU looks like

SOTYKTU is pink, round, biconvex, film-coated tablet laser printed with "BMS 895 6 mg" on one side in two lines and no content on the other side (AUST R 376290).

Each pack contains 7 or 28 film-coated tablets.

Who distributes SOTYKTU

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

This leaflet was prepared in September 2026.

SOTYKTU is a trademark of Bristol-Myers Squibb Company.