

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SOTYKTU**®

Deucravacitinib tablets

This Patient Medication Information is written for the person who will be taking **SOTYKTU**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SOTYKTU**, talk to a healthcare professional.

What **SOTYKTU** is used for:

- **SOTYKTU** is used to treat adults with moderate to severe plaque psoriasis. It is used in those patients who may benefit from taking pills, injection or treatment with light called phototherapy.

How **SOTYKTU** works:

SOTYKTU works by blocking “TYK2”, a protein involved in inflammation seen with psoriasis.

SOTYKTU improves skin clearance, reduces symptoms of psoriasis (such as itch, pain, stinging, burning and skin tightness).

The ingredients in **SOTYKTU** are:

Medicinal ingredient(s): deucravacitinib

Non-medicinal ingredients: anhydrous lactose, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, Opadry® II Pink (iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide), silicon dioxide.

SOTYKTU comes in the following dosage form(s):

As 6 mg tablets.

Do not use **SOTYKTU** if:

- are allergic to deucravacitinib or to any of the ingredients in **SOTYKTU**
- are less than 18 years of age. This is because safety and efficacy have not been established.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take **SOTYKTU. Talk about any health conditions or problems you may have, including if you:**

- have an infection including one that doesn't go away or often comes back. You should not take **SOTYKTU** if you have an active infection.

- have or have ever had tuberculosis (TB).
- have recently had or plan to have a vaccination. You should not receive a live vaccine while you are taking SOTYKTU.
- have liver problems. SOTYKTU is not recommended if you have severe liver problems.
- are taking other medicines that affect your immune system called immunosuppressants.
- are pregnant, think you may be pregnant or are planning to have a baby. It is not known how this medicine will affect the baby.
- are breast-feeding or are planning to breast-feed. It is not known if SOTYKTU will affect your baby.

Pregnancy Registry: There is a registry for pregnant women exposed to SOTYKTU. The purpose of this registry is to collect information about your health and your baby's health. You can sign-up directly or your healthcare provider can refer you to this registry by calling 1-877-311-8972 or visiting <https://mothertobaby.org/ongoing-study/sotyktu-deucravacitinib/>.

Other warnings you should know about:

Infections: Before you take SOTYKTU, tell your healthcare professional if you have an infection including one that doesn't go away or often comes back. You should not take SOTYKTU if you have an active infection. SOTYKTU can make you more likely to get an infection or make an infection worse. Talk to your healthcare professional if you have any symptoms of an infection before you start taking SOTYKTU or while you are taking it. These include:

- fever, sweats, or chills
- flu-like symptoms
- muscle aches
- weight loss
- cough
- sore throat
- shortness of breath
- blood in your phlegm (mucus)
- warm, red, or painful skin or sores on your body, different from your psoriasis
- diarrhea or stomach pain
- burning when you urinate or urinating more often than normal
- feeling very tired

Tuberculosis: Before you take SOTYKTU, tell your healthcare professional if you have or have ever had tuberculosis (TB). You should not take SOTYKTU if you have an active TB infection. Your healthcare professional may treat you for TB before you take SOTYKTU if you have TB or have had it before.

Lactose: SOTYKTU contains lactose. If you have been told by your doctor that you have one of the following rare hereditary diseases you should not take SOTYKTU: Galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may [also] interact with SOTYKTU:

- Vaccines. Tell your doctor if you have recently received or will receive a vaccine. You should not receive live vaccines while taking SOTYKTU.
- Some medicines that affect your immune system known as immunosuppressants.

How to take SOTYKTU:

- Take SOTYKTU exactly as your healthcare professional tells you to.
- Swallow the tablet whole with water. Do not crush, cut, or chew the tablets.
- Take SOTYKTU with or without food.
- Check with your healthcare professional if you are not sure how to take SOTYKTU.

Usual dose:

Adult: Take one tablet once a day.

Your doctor will decide for how long you need to take SOTYKTU.

Overdose:

If you think you, or a person you are caring for, have taken too much SOTYKTU, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll free number 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

Missed dose:

If you forget to take SOTYKTU just take the usual dose the next day. Never take a double dose to make up for a missed dose.

Possible side effects from using SOTYKTU:

These are not all the possible side effects you may have when taking SOTYKTU. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- **acne-like rash:** red bumps filled with pus, tender, painful or itchy skin, crusts on skin on the face and trunk.
- **folliculitis** (inflamed hair pores): small bumps or pimples, blisters, itchy, burning or painful skin.
- **oral ulcers:** painful sores on inside of lips, gums, tongue, or roof of the mouth.
- **viral infection of the mouth** (cold sores): painful, fluid-filled blisters on lips or nose

Certain kinds of cancer have been reported in people taking SOTYKTU. It is not known if SOTYKTU increases your chance of getting cancer.

SOTYKTU may cause abnormal blood test results. Your doctor may perform blood tests and will interpret the results.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Herpes simplex (infection caused by the herpes simplex virus): pain or itching around your mouth or in your genital area, small red or tiny blisters or sores (men: penis, scrotum) (women: vaginal area, labia).		✓	
Uncommon			
Infections: fever, sweats, or chills, muscle aches, flu-like symptoms, cough, sore throat, shortness of breath, blood in your phlegm (mucus), diarrhea or stomach pain, warm, red, or painful skin or sores on your body, different from your psoriasis, burning when you urinate or urinating more often than normal, feeling tired weight loss.		✓	
Rare			
Herpes Zoster (shingles): a painful skin rash of fluid-filled blisters, blisters appear along a strip of skin, itching.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature between 15°C and 30°C.

Keep out of reach and sight of children.

If you want more information about SOTYKTU:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)) the manufacturer's website www.bms.com/ca/en; or by calling 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada.

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