

# SOTYKTU 6MG FILM-COATED TABLETS

Deucravacitinib (6mg)

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## What SOTYKTU film-coated tablets is used for

SOTYKTU contains the active substance deucravacitinib, which belongs to a group of medicines called tyrosine kinase 2 (TYK2) inhibitors that help to reduce inflammation associated with psoriasis.

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 your scalp and nails, hands, and feet.

## How SOTYKTU film-coated tablets works

SOTYKTU works by selectively blocking the activity of an enzyme called ‘TYK2’ (tyrosine kinase 2) which is involved in the process of inflammation. By reducing the activity of this enzyme, SOTYKTU can help to control the inflammation associated with plaque psoriasis and thereby reduce the signs (skin dryness, cracking, scaling, shedding, or flaking, redness and bleeding) and can therefore help to reduce symptoms such as itching, pain, burning, stinging, and skin tightness of this condition.

SOTYKTU has also been shown to improve the quality of life in patients with

psoriasis. This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

## Before you use SOTYKTU film-coated tablets

### - When you must not use it

#### Do not take SOTYKTU

- if you are allergic to deucravacitinib or any of the other ingredients of this medicine.
- if you have an infection, including active tuberculosis (TB) which your doctor thinks is important.

### - Before you start to use it

#### Warnings and precautions

Talk to your doctor or pharmacist before taking SOTYKTU:

- if you currently have an infection that does not go away or that keeps coming back
- if you have or have ever had tuberculosis (TB)
- if you have cancer, because your doctor will have to decide if you can still be given SOTYKTU
- if you have heart problems or medical conditions that make you more likely to develop heart disease - it is not clear if SOTYKTU increases the risk of heart disease
- if you have had or are at risk of blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins. It is not clear if SOTYKTU increases the risk of blood clots
- if you have recently had or plan to have a vaccination.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using SOTYKTU.

### - Taking other medicines

Tell your doctor or pharmacist:

- if you are taking, have recently taken or might take any other medicines
- if you recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using SOTYKTU.

## How to use SOTYKTU film-coated tablets

### - How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 6 mg taken every day. The tablet should be swallowed whole and can be taken either with or without food. Do not crush, cut, or chew the tablets.

### - When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### - How long to use it

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

If your condition has not improved after six months of treatment, talk to your doctor.

Do not stop taking SOTYKTU without talking to your doctor first. If you stop treatment, symptoms of psoriasis may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### - If you forget to use it

If you forgot to take SOTYKTU, just take the normal dose the next day. Do not take a double dose to make up for a forgotten tablet.

### - If you use too much (overdose)

If you have taken more SOTYKTU than you should, talk to your doctor as soon as

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possible. You may get some of the side effects listed in section Side effects.

## While you are using SOTYKTU film-coated tablets

### - Things you must do

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, 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.

### - Things you must not do

#### **Children and adolescents**

SOTYKTU is **not recommended** for children and adolescents under 18 years of age because it has not been evaluated in this age group.

### - Things to be careful of

#### **Driving and using machines**

SOTYKTU is not expected to affect your ability to drive or use machines.

#### **SOTYKTU contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### **SOTYKTU contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

#### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Very common** (may affect more than 1 in 10 people)

- upper respiratory tract (nose and throat) infections with symptoms such as sore throat and stuffy nose

**Common** (may affect up to 1 in 10 people)

- viral infection of the mouth (such as cold sores)

- an increase in the level of an enzyme in your blood called creatine phosphokinase (CPK)
- sores in mouth
- acne-like rashes
- inflammation of hair follicles

**Uncommon** (may affect up to 1 in 100 people)

- shingles (*herpes zoster*)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of SOTYKTU film-coated tablets

### - Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use this medicine if you notice the tablets are damaged or there are signs of tampering with the medicine packaging.

### - Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## Product Description

### - What it looks like

SOTYKTU is a pink, round, biconvex, film-coated tablet printed with "BMS 895" and "6 mg" on one side, in two lines, plain on the other side.

The film-coated tablets are provided in blisters containing 7 or 14 tablets.

Each pack contains 7 or 28 film-coated tablets.

Not all pack sizes may be marketed.

### - Ingredients

#### - Active ingredients (s)

The active substance is deucravacitinib. Each film coated tablet contains 6 mg of deucravacitinib.

#### - Inactive ingredients

The other ingredients are

- tablet core: hypromellose acetate succinate, anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, colloidal hydrated silica and magnesium stearate.
- film-coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide red (E172) and iron oxide yellow (E172).

### - MAL number:

MAL XXXXXXXX

## Manufacturer

Patheon Inc.  
2100 Syntex Court  
Mississauga, Ontario, L5N 7K9  
Canada

## Product Registration Holder

DKSH Malaysia Sdn Bhd  
B-11-01, The Ascent, Paradigm  
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21/03/2024

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