Package leaflet: Information for the patient

SOTYKTU 6 mg film-coated tablets
deucravacitinib

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SOTYKTU is and what it is used for

What SOTYKTU is
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.

What SOTYKTU is used for
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 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.

2. What you need to know before you take SOTYKTU

Do not take SOTYKTU
- if you are allergic to deucravacitinib or any of the other ingredients of this medicine (listed in section 6).

- if you have an infection, including active tuberculosis (TB) which your doctor thinks is important.

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.

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.

Other medicines and SOTYKTU
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.

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.

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’.

3. How to take SOTYKTU

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.

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.

If you take more SOTYKTU than you should
If you have taken more SOTYKTU than you should, talk to your doctor as soon as possible. You may get some of the side effects listed in section 4.

If you forget to take SOTYKTU
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 stop taking SOTYKTU
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.

4. Possible 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*)

Reporting of side effects
If you get any side effects, talk to your doctor, nurse, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store SOTYKTU

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.

This medicine does not require any special storage conditions.

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

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.

6. Contents of the pack and other information

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

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).

What SOTYKTU looks like and contents of the pack
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 calendar or non-calendar blisters containing 7 or 14 tablets. Each pack contains 7, 14, 28 or 84 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bristol-Myers Squibb Pharma EEIG
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Ireland

Manufacturer
Swords Laboratories Unlimited Company
T/A Bristol-Myers Squibb Pharmaceutical Operations
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