Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine is dispensed with a doctor's prescription only

SOTYKTU 6 mg
Film-coated tablets

Name and quantity of active ingredient:
Each film-coated tablet contains 6 mg deucravacitinib

Inactive ingredients and allergens in this medicine - see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

SOTYKTU is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Therapeutic group: immunosuppressants

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.

Plaque psoriasis is 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 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 reduces 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.

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. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to deucravacitinib or any of the other ingredients of this medicine (listed in section 6).
- you have an infection, including active tuberculosis (TB), which the doctor thinks is important.

Special warnings about using this medicine
Before using SOTYKTU, tell your doctor or pharmacist if:
- you currently have an infection that does not go away or that keeps coming back
- you have or have ever had tuberculosis (TB)
- you have cancer, because the doctor will have to decide if you can still be given SOTYKTU
- you have heart problems or a medical condition that make you more likely to develop heart disease – it is not clear if SOTYKTU increases the risk of heart disease
- you have had or are at risk of blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell the 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
- you have recently had or plan to have a vaccination

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

Children and adolescents
SOTYKTU is not intended for children and adolescents under 18 years of age. There is no information about the safety and efficacy of using this medicine in children and adolescents.

Interactions with other medicines
- **Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescription medicines and dietary supplements.**
- **Tell the doctor or pharmacist** if you recently had or plan to have a vaccination.
  You should not be given a certain type of vaccines (live vaccines) while you are using SOTYKTU.

Using this medicine and food
You can take this tablet either with or without food.

Pregnancy and breast-feeding
Pregnancy:
If you are pregnant, think you may be pregnant or are planning to have a baby, ask the doctor for advice before taking this medicine. This is because it is not known if SOTYKTU will affect your unborn baby.
Breast-feeding:
It is not known whether SOTYKTU passes into breast milk, so risk to the breastfed newborn or infant cannot be excluded. If you are breast-feeding or planning to breast-feed, ask your doctor whether to stop breast-feeding or avoid taking this treatment.

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

Important information about some of this medicine's ingredients
SOTYKTU contains lactose
If you have been told by the doctor that you have an intolerance to some sugars, contact the 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 use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dose is usually one tablet (6 mg) taken every day.
Do not exceed the recommended dose.

Taking this medicine
- Swallow the tablet whole
- You can take the tablet either with or without food
- Do not crush, cut, or chew the tablets

Treatment duration
The doctor will decide for how long you need to use SOTYKTU.

If your condition has not improved after 6 months of treatment, talk to the doctor.

If you have accidentally taken a higher dose of SOTYKTU, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
You may get some of the side effects listed in section 4.

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

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

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

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using SOTYKTU may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Very common side effects – affect more than one in ten users:
- upper respiratory tract (nose and throat) infections with symptoms such as sore throat and stuffy nose

Common side effects – affect 1–10 in 100 users:
- 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 side effects – affect 1–10 in 1,000 users:
- shingles (herpes zoster)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the blister tray and carton. The expiry date refers to the last day of that month.

Storage conditions
- 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 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. Additional information

In addition to the active ingredient, this medicine also contains:
- Inactive ingredients (tablet core):
  Microcrystalline cellulose (PH-102), anhydrous lactose, hypromellose acetate succinate, croscarmellose sodium, silica colloidal hydrated, magnesium stearate.
- Film-coating contains:
  Polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide red, iron oxide yellow.

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

The film-coated tablets are provided in blister trays containing either 7 or 14 tablets.
Each pack contains 28 film-coated tablets.

Registration holder's name and address
Bristol-Myers Squibb (Israel) Ltd.,
18 Aharon Bart St., P.O Box 3361,
Kiryat Arye,
Petach Tikva

Manufacturer's name and address
Bristol-Myers Squibb Company
Route 206 & Province Line Road, Princeton,
New Jersey 08543, USA

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Registration number of the medicine in the Ministry of Health's National Drug Registry:
SOTYKTU 6 mg: 175-38-37671-99