

## Package leaflet: Information for the patient

### Brinsupri 25 mg film-coated tablets brensocatib

▼ 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 Brinsupri is and what it is used for
2. What you need to know before you take Brinsupri
3. How to take Brinsupri
4. Possible side effects
5. How to store Brinsupri
6. Contents of the pack and other information

#### **1. What Brinsupri is and what it is used for**

##### **What Brinsupri is**

Brinsupri contains the active substance brensocatib, which belongs to the class of medicines called dipeptidyl peptidase 1 (DPP1) inhibitors.

##### **What Brinsupri is used for**

Brinsupri is used to treat patients 12 years and older with non-cystic fibrosis bronchiectasis (NCFB) who have experienced two or more flare-ups or worsening of symptoms (also known as exacerbations) in the past 12 months. NCFB is a long-term (chronic) condition where the airways of the lungs are damaged, causing a cough with mucus production.

##### **How Brinsupri works**

Brinsupri targets a protein called DPP1, which is involved in the process that causes inflammation in the lungs. By blocking the activity of this protein, the medicine prevents flare-ups in the lungs and may improve some symptoms of NCFB.

#### **2. What you need to know before you take Brinsupri**

**Do not take Brinsupri** if you are allergic to brensocatib or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Brinsupri if you have recently had or plan to have a vaccination.

### **Children and adolescents**

Do not give this medicine to children under 12 years of age because its safety and benefits are not known in children in this age group.

### **Other medicines and Brinsupri**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **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.

Benefits and potential risks of use of Brinsupri during pregnancy have not been established. Brinsupri may be used during pregnancy where the expected benefit to the mother outweighs the unknown risk to the unborn child. Your doctor will discuss this with you.

There is not enough information to say whether the medicine passes into human breast milk. A decision must be made whether to stop breast-feeding or to stop using Brinsupri, based on the benefit of breast-feeding for the child and the benefit of treatment for the mother. Your doctor will discuss this with you.

### **Driving and using machines**

Brinsupri is unlikely to affect your ability to drive and use machines.

### **Brinsupri 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 Brinsupri**

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 for adults and adolescents aged 12 years and older is one 25 mg tablet taken by mouth once daily with or without food.

### **If you take more Brinsupri than you should**

If you take more Brinsupri than you should, seek urgent medical attention, taking the medicine packaging with you.

### **If you forget to take Brinsupri**

Take your next dose at the usual time the next day. Do not take a double dose to make up for a forgotten tablet.

### **If you stop taking Brinsupri**

You should not stop taking Brinsupri without discussing this with your doctor.

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.

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

- nose and throat infection (upper respiratory tract infection)

- diarrhoea and vomiting (gastroenteritis)
- headache
- problems affecting the gums, including red, swollen and bleeding gums (gingival disorder)
- inflammation and infection of the gum and bone surrounding the teeth (periodontal disease)
- small areas of skin thickening (hyperkeratosis)
- rash
- dry skin
- inflammation of the skin (dermatitis)
- shedding dead cells from the skin's outer layer (skin exfoliation)
- hair loss (alopecia).

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Brinsupri**

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 carton after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice the tablets are damaged or if 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 Brinsupri contains**

- The active substance is brensocatib. Each film-coated tablet contains 25 mg of brensocatib (as monohydrate).
- The other ingredients are:  
Tablet core: cellulose, microcrystalline; calcium hydrogen phosphate dihydrate; sodium starch glycolate; silica, colloidal hydrated; and glycerol dibehenate. See section 2 'Brinsupri contains sodium' for further information.  
Film-coating: poly(vinyl alcohol); titanium dioxide; macrogol; talc; and black iron oxide (E172).

### **What Brinsupri looks like and contents of the pack**

Brinsupri 25 mg film-coated tablets (tablets) are round, grey tablets approximately 9 mm in diameter, with "25" on one side and "BRE" on the other side.

The film-coated tablets are provided in aluminium foil blister cards containing 14 film-coated tablets. Each pack contains 28 film-coated tablets.

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