Patient Information BRINSUPRI (brin-SOO-pree) (brensocatib) tablets, for oral use

What is BRINSUPRI?

BRINSUPRI is a prescription medicine used to treat non-cystic fibrosis bronchiectasis (NCFB) in adults and children 12 years of age and older. It is not known if BRINSUPRI is safe and effective in children under 12 years of age.

Before taking BRINSUPRI, tell your healthcare provider about all of your medical conditions, including if you:

- have recently received or are scheduled to receive any live attenuated vaccinations.
- are pregnant or plan to become pregnant. It is not known if BRINSUPRI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if BRINSUPRI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not change or stop your medicines unless your healthcare provider tells you to.

How should I take BRINSUPRI?

- Take BRINSUPRI exactly as your healthcare provider tells you to take it.
- Take 1 BRINSUPRI tablet by mouth daily with or without food.
- If you forget to take a dose of BRINSUPRI, take your next dose at your regular time the next day.
- Do not double the dose to make up for the missed dose.

What are the possible side effects of BRINSUPRI? BRINSUPRI may cause serious side effects including:

- **Skin problems.** Tell your healthcare provider about any new skin symptoms. Your healthcare provider may send you to a dermatologist for an examination if needed.
- **Dental problems.** Get regular dental checkups while taking BRINSUPRI. Brush and clean your teeth as recommended by your dentist. Tell your healthcare provider and contact your dentist if you experience new gum (gingival) or teeth (dental) symptoms.

Common side effects of BRINSUPRI include:

- upper respiratory tract infection
- headache
- rash

- dry skin
- small areas of skin thickening (hyperkeratosis)
- high blood pressure (hypertension)

Less common side effects include abnormal liver blood test, hair loss (alopecia), and skin cancers. These are not all of the possible side effects of BRINSUPRI.

Call your doctor for medical advice about side effects. You may also report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store BRINSUPRI?

- Store BRINSUPRI at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep BRINSUPRI in its original bottle.

Keep BRINSUPRI and all medicines out of the reach of children.

General information about the safe and effective use of BRINSUPRI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BRINSUPRI for a condition for which it was not prescribed. Do not give BRINSUPRI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BRINSUPRI that is written for health professionals.

What are the ingredients in BRINSUPRI?

Active ingredient: brensocatib monohydrate

Inactive ingredients: dibasic calcium phosphate dihydrate, glyceryl dibehenate, microcrystalline cellulose, silicon dioxide, and sodium starch glycolate

Film coating: ferrosoferric oxide/black iron oxide, iron oxide yellow, and iron oxide red or ferrosoferric oxide/black iron oxide, macrogol/PEG, polyvinyl alcohol-partially hydrolyzed, talc, and titanium dioxide

Manufactured for: Insmed Incorporated, Bridgewater, NJ 08807

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For more information, go to www.BRINSUPRI.com or call 1-844-4-INSMED (1-844-446-7633).

This Patient Information has been approved by the U.S. Food and Drug Administration

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