

## Package leaflet: Information for the patient

### Ekterly 300 mg film-coated tablets sebetralstat

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

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

Ekterly is a medicine that contains the active substance sebetralstat.

Ekterly is used to treat attacks of hereditary angioedema in adults and adolescents aged from 12 years.

#### **What Hereditary Angioedema is**

Hereditary angioedema is a condition that often runs in families. In hereditary angioedema your blood does not have enough of a protein called C1 inhibitor, or the protein does not work properly. This leads to too much of the enzyme 'plasma kallikrein', which in turn increases the levels of 'bradykinin' in your bloodstream. Too much bradykinin leads to attacks of swelling and pain in different parts of your body.

#### **How Ekterly works**

Ekterly works by blocking the activity of plasma kallikrein and helps reduce the levels of bradykinin. When taken at the start, or during an attack, this will stop further progression of the attack and the symptoms of swelling and pain.

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

##### **Do not take Ekterly**

- if you are allergic to sebetralstat or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

After taking Ekterly for a laryngeal attack it is important to seek immediate medical attention.

If you have severely reduced liver function talk to your doctor before taking Ekterly as this medicine may not be suitable for you.

## **Children**

Ekterly is not recommended in children under 12 years. This is because it has not been studied in this age group.

## **Other medicines and Ekterly**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some other medicines can affect the way Ekterly works.

In particular, tell your doctor or pharmacist if you are taking the following:

- antibiotic medicines (e.g. rifampicin, clarithromycin)
- some medicines for fungal infections (e.g. itraconazole, ketoconazole)
- antiviral medicines (e.g. efavirenz, ritonavir, saquinavir)
- some medicines used for epilepsy (e.g. carbamazepine, phenytoin, phenobarbital)
- some medicines for high blood sugars (e.g. metformin).

If you are not sure, talk to your doctor or pharmacist before taking Ekterly.

## **Ekterly with food and drink**

This medicine can be taken with or without food (see Section 3).

## **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

## **Driving and using machines**

Do not drive or use machines if you feel tired as a result of your HAE attack or after using Ekterly.

## **Ekterly contains croscarmellose sodium**

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

## **3. How to take Ekterly**

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

**Adults and adolescents aged 12 years and over:** The recommended dose is **ONE tablet** to be taken at the earliest sign that you are having an attack. Swallow the tablet whole with some water, if required. The tablet can be taken with or without food.

An additional dose of ONE tablet may be taken if symptoms persist.

If you are taking strong CYP3A4 inhibitors such as itraconazole your doctor will prescribe taking a single tablet when treating an attack.

If you are taking strong or moderate CYP3A4 inducers such as phenytoin or efavirenz your doctor will prescribe taking three tablets together when treating an attack. No more than three tablets should be taken in 24 hours (i.e. patients taking strong or moderate CYP3A4 inducers).

## **Use in children**

Ekterly is not recommended for use in children under 12 years of age because it has not been studied in these patients.

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

Tell your doctor immediately if you have taken too many Ekterly tablets.

#### **4. Possible side effects**

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

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

- Headache
- Indigestion

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

- Feeling sick (nausea)
- Abdominal pain
- Feeling unusually tired or weak (fatigue)
- Back pain
- Hot flush

#### **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, Website: [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 Ekterly**

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 and blister wallet after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Ekterly contains**

- The active substance is sebetralstat.
- The other ingredients are:  
Tablet core: microcrystalline cellulose; croscarmellose sodium; povidone K30; magnesium stearate.  
Film-coatings: Macrogol poly(vinyl alcohol) grafted copolymer; talc; titanium dioxide (E171); glycerol monocaprylocaprate (Type 1); poly(vinyl alcohol); iron oxide yellow (E172); iron oxide black (E172); maltodextrin; guar galactomannan; hypromellose; triglycerides, medium chain.

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

Ekterly 300 mg tablets are yellow, oval, biconvex tablets debossed with KalVista logo “K” on one side and “300” on the other side. The tablets are packed in a blister encased in a child-resistant cardboard wallet. The wallets are contained in a cardboard box. The pack contains 4 or 6 tablets. Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder:**

KalVista Pharmaceuticals Ltd.  
Porton Science Park  
Bybrook Road, Porton Down  
Salisbury SP4 0BF

### **Manufacturer:**

Almac Pharma Services Limited  
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**This leaflet was last revised in 07/2025.**