

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aprepitant zentiva 125mg hard capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you are the parent of a child taking aprepitant, please read this information carefully.

- 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 or the child 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 or the child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:

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

1. What aprepitant is and what it is used for

Aprepitant contains the active substance aprepitant and belongs to a group of medicines called “neurokinin 1 (NK1) receptor antagonists”. The brain has a specific area that controls nausea and vomiting. Aprepitant works by blocking signals to that area, thereby reducing nausea and vomiting.

Aprepitant capsules are used in adults and adolescents from the age of 12 years **in combination with other medicines** to prevent nausea and vomiting caused by medicines used in chemotherapy (cancer treatment) that are strong and moderate triggers of nausea and vomiting (such as cisplatin, cyclophosphamide, doxorubicin or epirubicin).

2. WHAT YOU NEED TO KNOW before you take or give aprepitant

Do not take aprepitant:

- if you or the child is allergic to aprepitant or any of the other ingredients of this medicine (listed in section 6).
- with medicines containing:
 - pimozide (used to treat psychiatric illnesses)
 - terfenadine and astemizole (used for hay fever and other allergic conditions)
 - cisapride (used for treating digestive problems).

Tell the doctor if you or the child are taking these medicines since the treatment must be modified before you or the child start taking aprepitant.

Warnings and precautions

Talk to the doctor, pharmacist or nurse before taking aprepitant or giving this medicine to the child. Before treatment with aprepitant, tell the doctor if you or the child have liver disease because the liver is important in breaking down this medicine in the body. The doctor may therefore have to monitor the condition of your or the child's liver.

Children and adolescents

Do not give aprepitant 80 mg and 125 mg capsules to children under 12 years of age, because the 80 mg and 125 mg capsules have not been studied in this population.

Other medicines and Aprepitant

Aprepitant can affect other medicines, both during and after treatment with aprepitant. There are some medicines that should not be taken with aprepitant (such as pimozide, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also ‘Do not take aprepitant’).

The effects of aprepitant or other medicines might be influenced if you or the child takes aprepitant together with other medicines including those listed below. Please talk to the doctor or pharmacist if you or the child is taking any of the following medicines:

- birth control medicines which can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones, may not work adequately when taken together with aprepitant. Another or additional non-hormonal form of birth control should be used during treatment with aprepitant and for up to 2 months after taking aprepitant
- cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants)
- alfentanil, fentanyl (used to treat pain)
- quinidine (used to treat an irregular heart beat)
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer)
- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines)
- warfarin, acenocoumarol (blood thinners; blood tests may be required)
- rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections)
- phenytoin (a medicine used to treat seizures)
- carbamazepine (used to treat depression and epilepsy)
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep)
- St. John's Wort (a herbal preparation used to treat depression)
- protease inhibitors (used to treat HIV infections)
- ketoconazole, except shampoo (used to treat Cushing's syndrome - when the body produces an excess of cortisol)
- itraconazole, voriconazole, posaconazole (antifungals)
- nefazodone (used to treat depression)
- corticosteroids (such as dexamethasone and methylprednisolone)
- anti-anxiety medicines (such as alprazolam)
- tolbutamide (a medicine used to treat diabetes)

Tell the doctor or pharmacist if you or the child is taking, has recently taken or might take any other medicines.

Pregnancy and breast-feeding

This medicine should not be used during pregnancy unless clearly necessary. If you or the child is pregnant or breast-feeding, think that they may be pregnant or are planning to have a baby, ask the doctor for advice before taking this medicine.

For information regarding birth control, see ‘Other medicines and aprepitant’.

It is not known whether aprepitant is excreted in human milk; therefore, breast-feeding is not recommended during treatment with this medicine. It is important that you tell the doctor if you or the child is breast-feeding or are planning to breast-feed before taking this medicine.

Driving and using machines

It should be taken into account that some people feel dizzy and sleepy after taking aprepitant. If you or the child feels dizzy or sleepy, avoid driving, riding a bicycle or using machines or tools after taking this medicine (see ‘Possible side effects’).

Aprepitant contains sucrose

Aprepitant capsules contain sucrose. If you or the child have been told by the doctor that you or the child has an intolerance to some sugars, contact the doctor before taking this medicine.

Aprepitant contains sodium

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

3. how to take aprepitant

Always take this medicine or give this medicine to the child exactly as the doctor, pharmacist or nurse has told you. Check with the doctor, pharmacist or nurse if you are not sure.

Always take aprepitant together with other medicines to prevent nausea and vomiting. After treatment with aprepitant, the doctor may ask you or the child to continue taking other medicines including a corticosteroid (such as dexamethasone) and a ‘5HT3 antagonist’ (such as ondansetron) for preventing nausea and vomiting. Check with the doctor, pharmacist or nurse if you are not sure.

The recommended dose of aprepitant is:

Day 1: one 125 mg capsule 1 hour before you start your chemotherapy session

and

Days 2 and 3: one 80 mg capsule each day

If no chemotherapy is given, take aprepitant in the morning.

If chemotherapy is given, take aprepitant 1 hour before you start your chemotherapy session.

This medicine is for oral use. Swallow the capsule whole with some liquid. Aprepitant can be taken with or without food.

If you take more aprepitant than you should

Do not take more capsules than prescribed by your doctor. If you or the child has taken too many capsules, contact your doctor immediately.

If you forget to take aprepitant

If you or the child has missed a dose, contact your doctor for advice.

If you have any further questions on the use of this medicine, ask the doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop taking aprepitant and see a doctor immediately if you or the child notices any of the following side effects, which may be serious, and for which you or the child may need urgent medical treatment:

- Hives, rash, itching, difficulty breathing or swallowing (frequency not known, cannot be estimated from the available data); these are signs of an allergic reaction.

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

- constipation, indigestion
- headache
- tiredness
- loss of appetite
- hiccups
- increased amount of liver enzymes in your blood

Uncommon: may affect up to 1 in 100 people

- dizziness, sleepiness
- acne, rash
- anxiousness
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind
- increased painful or burning urination
- weakness, generally feeling unwell
- hot flush/reddening of the face or skin
- fast or irregular heartbeats
- fever with increased risk of infection, lowering of red blood cells

Rare: may affect up to 1 in 1000 people

- difficulty thinking, lack of energy, taste disturbance
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin, itching rash, Stevens-Johnson syndrome/toxic epidermal necrolysis (rare severe skin reaction)
- euphoria (feeling of extreme happiness), disorientation
- bacterial infection, fungal infection
- severe constipation, stomach ulcer, inflammation of the small intestine and colon, sores in mouth, bloating
- frequent urination, passing more urine than normal, presence of sugar or blood in urine
- chest discomfort, swelling, change in the manner of walking
- cough, mucus in back of throat, throat irritation, sneezing, sore throat
- eye discharge and itching
- ringing in the ear
- muscle spasms, muscle weakness
- excessive thirst
- slow heartbeat, heart and blood vessel disease
- lowering of white blood cells, low sodium levels in the blood, weight loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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 Aprepitant

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 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 remove the capsule from its blister until you are ready to take it.

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 aprepitant contains:**

- The active substance is aprepitant.
Each 125 mg capsule contains 125 mg of aprepitant
- The other ingredients are hypromellose, poloxamer, sucrose, microcrystalline cellulose, gelatin, sodium laurilsulfate (E487), titanium dioxide (E171), shellac, iron oxide black (E172), propylene glycol (E1520).
The 125 mg capsule also contains iron oxide red (E172).

What aprepitant looks like and contents of the pack:

The 125 mg hard capsules are presented as opaque hard gelatin capsules of size No 1, with a pink cap and white body, imprinted in black ink with “125mg” on the body.

Aprepitant is packed in a cardboard box containing the appropriate number of OPA/ALU/PVC - Aluminium foil blisters with an instruction leaflet.

Aprepitant 125 mg hard capsules are supplied in the following pack sizes:

- 5 Aluminium blisters each containing one 125 mg capsule

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