Package leaflet: Information for the user

Aprepitant 125 mg and 80 mg hard capsules
aprepitant

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 capsules, 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 gets 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 capsules are and what they are used for
2. What you need to know before you take or give Aprepitant capsules
3. How to take Aprepitant capsules
4. Possible side effects
5. How to store Aprepitant capsules
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1. What Aprepitant capsules are and what they are used for

Aprepitant capsules contain the active substance aprepitant and belong to a group of medicines called "neurokinin 1 (NK_1) receptor antagonists". The brain has a specific area that controls nausea and vomiting. Aprepitant capsules work 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 capsules

Do not take Aprepitant capsules:
- 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 is taking these medicines since the treatment must be modified before you or the child starts taking Aprepitant capsules.

Warnings and precautions
Talk to the doctor, pharmacist or nurse before taking Aprepitant capsules or giving this medicine to the child.

Before treatment with Aprepitant capsules, tell the doctor if you or the child has 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 capsules
Aprepitant capsules can affect other medicines both, during and after treatment with Aprepitant capsules. There are some medicines that should not be taken with Aprepitant capsules (such as pimozide, terfenadine, astemizole, and cisapride) or that require a dose adjustment (see also 'Do not take Aprepitant capsules').

The effects of Aprepitant capsules or other medicines might be influenced if you or the child takes Aprepitant capsules 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 capsules. Another or additional non-hormonal form of birth control should be used during treatment with Aprepitant capsules and for up to 2 months after taking Aprepitant capsules
- 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 may be pregnant or is planning to have a baby, ask the doctor for advice before taking this medicine.

For information regarding birth control, see 'Other medicines and Aprepitant capsules'.

It is not known whether Aprepitant capsules are 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 is 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 capsules. 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 capsules contain sucrose
Aprepitant capsules contain sucrose. If you or the child has been told by the doctor that you or the child has an intolerance to some sugars, contact the doctor before taking this medicine.

Aprepitant capsules contain 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 capsules

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 capsules together with other medicines to prevent nausea and vomiting. After treatment with Aprepitant capsules, the doctor may ask you or the child to continue taking other medicines including a corticosteroid (such as dexamethasone) and a '$5HT_3$ 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 capsules 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 capsules in the morning.
If chemotherapy is given, take Aprepitant capsules 1 hour before you start your chemotherapy session.

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

If you take more Aprepitant capsules 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 capsules
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 capsules 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 1,000 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 or the child gets 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 Yellow Card Scheme, website: 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 capusles

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 the 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 capsules contain
- The active substance is aprepitant.
  Each 125 mg capsule contains 125 mg of aprepitant.
  Each 80 mg capsule contains 80 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 capsules look 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.
The 80 mg hard capsules are presented as opaque hard gelatin capsules of size No 2, with a white cap and white body, imprinted in black ink with "80mg" on the body.

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

Aprepitant 125 mg and 80 mg hard capsules are supplied in the following pack sizes:
- 3-day treatment pack containing one 125 mg capsule and two 80 mg capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pharmathen SA, 6 Dervenakion str., 15351 Pallini Attiki, Greece

Manufacturer
Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300, Greece

Pharmathen SA, 6 Dervenakion str., 15351 Pallini Attiki, Greece

Distributor
Northumbria Pharma Ltd.
NETpark
Thomas Wright Way
Sedgefield
Stockton-on-Tees
TS21 3FD
United Kingdom

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