What is in this leaflet

What Aprepitant Capsules are and what they are used for

What you need to know before you take or give Aprepitant Capsules

How to take Aprepitant Capsules

Possible side effects

How to store Aprepitant Capsules

Contents of the pack and other information

What to do if you take too much of Aprepitant Capsules

Do not take Aprepitant Capsules:

What if you have any further questions, ask your doctor, pharmacist or nurse. This includes any possible effects not listed in this leaflet.

Possible side effects

Driving and using machines

Aprepitant Capsules contain the active substance aprepitant and belonging to a group of medicines called “neurokinin 1 (NK1) receptor antagonists”. They work by blocking signals to that area of the brain that controls nausea and vomiting.

The effects of Aprepitant Capsules or other medications may be enhanced if you or your child takes Aprepitant Capsules together with the following medicines which are not listed in this leaflet. Please talk to the doctor or pharmacist if you are not sure:

•  with medicines containing: pimozide, midazolam, triazolam, phenobarbital (used to treat certain seizures; also used to treat depression and anxiety; also used to treat epilepsy),
•  itraconazole, voriconazole, posaconazole (infections; also used to treat depression),
•  ketoconazole, except shampoo (used to treat dandruff; also used to treat fungal infections; also used to treat skin disease),
•  protease inhibitors (used to treat HIV infections),
•  cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
•  dexamethasone, triamcinolone acetonide (used to treat inflammatory conditions; also used to treat arthritis; also used to treat immune system disorders),
•  nefazodone (used to treat depression),
•  terfenadine, astemizole, and cisapride (used for hay fever and other allergic conditions),
•  piperazine, enalapril (used to treat hypertension; also used to treat angina),
•  a corticosteroid (such as dexamethasone) and doxorubicin or cisplatin, cyclophosphamide, doxorubicin or cyclosporine (used to treat cancer),
•  astatin or radiotherapy (used to treat cancer),
•  a virus, bacterial or fungal infection or other infections (used to treat severe infections; also used to treat colds or other infections).

Follow the doctor's instructions. This medicine should not be used during treatment with Aprepitant Capsules for up to 2 months after taking Aprepitant Capsules:

•  cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
•  alfentanil, fentanyl (used to treat pain),
•  ketorolac (used to treat pain; also used to treat inflammation),
•  irinotecan, etoposide, vinorelbine, ifosfamide (antineoplastic agents; also used to treat cancer).
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**How to store Aprepitant Capsules**

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 blister and 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 remove the capsule from the 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.

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**Contents of the pack and other information**

**What Aprepitant Capsules contain**

• The active substance is aprepitant.

• The other ingredients are hypromellose, polysorbate, sorbic acid, microcrystalline cellulose, gelatin, sodium stearyl fumarate (E452), titanium dioxide (E171), shellac, iron oxide black (E172), propylene glycol (E1520). The 125mg capsules also contain iron oxide red (E162).

**What Aprepitant Capsules look like and contents of the pack**

The 125/80mg capsules are presented as opaque hard gelatin capsules of size No 1, with a pink cap and white body, imprinted in black with “125 mg” on the body. The 80mg hard capsules are presented as opaque hard gelatin capsules of size No 2, with a white cap and white body, imprinted in black red with “80mg” on the body.

Aprepitant Capsules are packed in a cardboard box containing the appropriate number of OPA/ALU/PVC/Aluminium foil with blister packs as an instruction leaflet.

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

• 5 Aluminium blisters each containing one 125mg hard capsule.

Aprepitant Capsule 80mg hard capsules are supplied in the following pack sizes:

• 2 treatment pack containing two 80mg capsules.

• 5 Aluminium blisters each containing one 80mg hard capsule.

Aprepitant Capsules 125mg and 80mg hard capsules are supplied in the following pack sizes:

• 3-day treatment pack containing one 125mg and 3 80mg capsules.

Not all pack sizes may be marketed.

**Manufacturing Authorisation holder**

Accord Healthcare Ireland Limited.

**UK-Eire-Artwork-Support@accord-healthcare.com**

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**Ingredients**

Aprepitant Capsules 80mg, 125mg & 125mg/80mg Hard Capsules PIL - UK/Eire

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**Side effects**

**Possible side effects**

- slow heartbeat, heart and blood vessel disease
- excessive thirst
- eye discharge and itching
- severe constipation, stomach ulcer, nausea, vomiting, heartburn, mouth sores, hiccups
- euphoria (feeling of extreme happiness), dizziness, sleepiness
- severe diarrhoea, stomach pain, dry mouth, passing wind
- increased amount of liver enzymes in your blood
- tiredness
- Hives, rash, itching, difficulty breathing or swelling

**Rare:** may affect up to 1 in 1,000 people

- fast or irregular heartbeats
- increased painful or burning urination
- anxiousness
- acne, rash
- dizziness, sleepiness
- signs of an allergic reaction.

**Common:** may affect up to 1 in 10 people

- nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind
- increased or painful or burning urination
- weakness, generally feeling unwell
- hot flushes/redness of the face or skin
- fast or irregular heartbeat
- having with increased risk of infection, lowering of red blood cells

**Rare:** may affect up to 1 in 50,000 people

- difficulty breathing, feeling anxious, feeling disturbed
- sensitivity of the skin to sun, excessive sweating, oily skin, sore skin, itching rash, Stevens-Johnson syndrome/toxic epidermal necrolysis (rare sensitive skin reaction)
- breathlessness (rare breathing problem), disorientation
- bacterial infection, fungal infection
- severe constipation, stomach ulcers, inflammation of the small intestines and colon, sore in mouth, blisters
- frequent urination
- a sickness that seems more acute than normal, presence of sugar or blood in urine
- chest discomfort, coughing, change in the manner of swallowing
- 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
- low blood pressure, heart and blood vessel disease
- lowering of white blood cells, low sodium levels in the blood, weight loss

**Reporting side effects**

If you or your child 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

Ireland:

HPRA Pharmacovigilance
Earlsfort Terrace
Irl – Dublin 2
Tel: +353 1 676 2517
Fax: +353 1 676 4971
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

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**Company**

Aprepitant 80mg, 125mg & 125mg/80mg Hard Capsules are supplied by Pharmathen S.A.

**Supplier**

Pharmathen S.A.

**Marketing Authorisation Holder**

Accord Healthcare Ireland Limited.

**Pack Size**

- 5 Aluminium blisters each containing one 125mg hard capsule.
- 2 treatment pack containing two 80mg capsules.
- 5 Aluminium blisters each containing one 80mg hard capsule.
- 3-day treatment pack containing one 125mg and 3 80mg capsules.

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**What**** Aprepitant Capsules do**

• Prevent nausea and vomiting. Check with your doctor, pharmacist or nurse if you are not sure.

**Applicable prescription**

If you take more Aprepitant Capsules than you should

- Do not take more capsules than prescribed by your doctor if you feel you have taken too many capsules, contact your doctor immediately.

**If you forget to take Aprepitant Capsules**

If you do not take a full course of this medicine, your symptoms may return or get worse and you may also have a lower chance of not experiencing nausea.

**Additional prescribing information**

Aprepitant Capsules are indicated for use in the following two conditions:

1. Chemotherapy-induced vomiting

2. Radiotherapy-induced vomiting

**If you or your child has missed a dose, contact your doctor or pharmacist as soon as possible.

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