

Package leaflet: Information for the user

EMEND® 125 mg powder for oral suspension aprepitant

Read all of this leaflet carefully before you start using this medicine because it contains important information. This leaflet has been written for the parent or carer who will give this medicine to the child - please read this information carefully.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor, pharmacist, or nurse.
- This medicine has been prescribed for the child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If the child gets any side effects, talk to the 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 EMEND is and what it is used for
2. What you need to know before you give EMEND
3. How to give EMEND
4. Possible side effects
5. How to store EMEND
6. Contents of the pack and other information

1. What EMEND is and what it is used for

EMEND contains the active substance ‘aprepitant.’ It belongs to a group of medicines called ‘neurokinin 1 (NK₁) receptor antagonists’.

The brain has a specific area that controls nausea and vomiting. EMEND works by blocking signals to that area, thereby reducing nausea and vomiting.

The powder for oral suspension is used in children aged 6 months to less than 12 years **in combination with other medicines** to prevent nausea and vomiting caused by 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 give EMEND

Do not give EMEND

- if the child is allergic to aprepitant or any of the other ingredients of this medicine (listed in section 6).
- if the child is using medicines that contain ‘pimozide’ (for mental health problems).
- if the child is using ‘terfenadine’ or ‘astemizole’ (for hay fever and other allergies).
- if the child is using ‘cisapride’ - (for problems with digestion).

Do not give this medicine if any of the above applies to the child and tell the child’s doctor if they are using any of the medicines above. This is because their treatment will need to be changed before starting this medicine. If you are not sure, talk to the doctor, pharmacist or nurse before giving this medicine.

Warnings and precautions

Talk to the doctor, pharmacist, or nurse before giving this medicine to the child.

Liver problems

Tell the doctor before treatment with EMEND starts, if the child has liver problems. This is because the liver is important in breaking down the medicine in the body. The doctor may have to check the condition of the child's liver during treatment.

Children and adolescents

Do not give EMEND powder for oral suspension to children under 6 months of age or who weigh less than 6 kg, or to adolescents between 12 and 18 years, because the powder for oral suspension has not been studied in this population.

Other medicines and EMEND

Tell the doctor, pharmacist or nurse if the child is using, has recently used or might use any other medicines. This is because EMEND can affect how other medicines work, during and after treatment with EMEND. Also, some other medicines can affect the way this medicine works.

Do not give EMEND and tell the doctor or pharmacist if the child is using any of the following medicines (see also 'Do not give EMEND'). This is because their treatment will need to be changed before starting EMEND:

- pimozide - for mental health problems,
- terfenadine and astemizole - for hay fever and other allergies,
- cisapride - for problems with digestion.

Do not give this medicine and tell the doctor or pharmacist if any of the above apply to the child.

Talk to the doctor, pharmacist or nurse if the child is taking any of the following medicines:

- medicines that affect the immune system – such as cyclosporine, tacrolimus, sirolimus, everolimus,
- alfentanil, fentanyl – for pain,
- quinidine – for irregular heartbeat,
- medicines for cancer – such as irinotecan, etoposide, vinorelbine, ifosfamide,
- medicines containing 'ergot alkaloid derivatives' - such as ergotamine and diergotamine - for migraines,
- medicines that thin the blood – such as warfarin, acenocoumarol. Your child may need blood tests during treatment with EMEND,
- antibiotics to treat infections – such as rifampicin, clarithromycin, telithromycin,
- phenytoin - for fits (seizures),
- carbamazepine - for depression and epilepsy,
- midazolam, triazolam, phenobarbital - to produce calmness or help you sleep,
- St. John's Wort - a herbal medicine for depression,
- protease inhibitors - for HIV infections,
- ketoconazole except shampoo (used to treat Cushing's syndrome - when the body produces an excess of cortisol),
- antifungal medicines such as itraconazole, voriconazole, posaconazole,
- nefazodone - for depression,
- corticosteroids - such as dexamethasone and methylprednisolone,
- medicines for anxiety such as alprazolam,
- tolbutamide - for diabetes,
- contraceptive medicines including pills, patches, implants, and some Intrauterine devices (IUDs) that release hormones. These may not work properly when taken with this medicine. You may need to use a different or an extra non-hormonal contraceptive during treatment with this medicine and for up to 2 months after treatment has finished.

If any of the above apply to the child (or you are not sure), talk to the doctor, pharmacist or nurse before giving this medicine.

Pregnancy and breast-feeding

This medicine should not be used during pregnancy and breast-feeding unless clearly necessary.

For information regarding pregnancy, breast-feeding and contraception, ask your doctor for advice.

Driving and using machines

It should be taken into account that some people may feel dizzy and sleepy after taking EMEND. If the child feels dizzy or sleepy, they should not ride a bicycle or use any tools or machines.

EMEND contains sucrose and lactose

The powder for oral suspension contains sucrose and lactose. If a doctor has told you that the child has an intolerance to some sugars, contact the doctor before giving this medicine to the child.

EMEND contains sodium

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

3. How to give EMEND

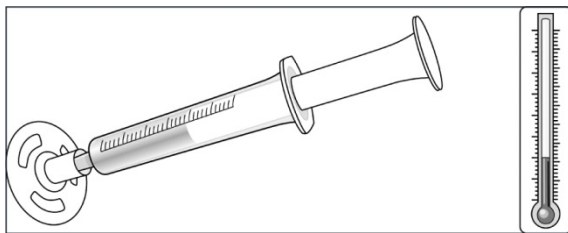
Healthcare professionals: See the instructions for preparation of the oral suspension for healthcare professionals at the end of this package leaflet. This tells you how to prepare a dose of EMEND as an oral suspension.

Parents and caregivers: Always give this medicine to the child exactly as the doctor, pharmacist or nurse has told you. Check with the child's doctor, pharmacist or nurse if you are not sure.

It is very important that this medicine is given exactly as directed below.

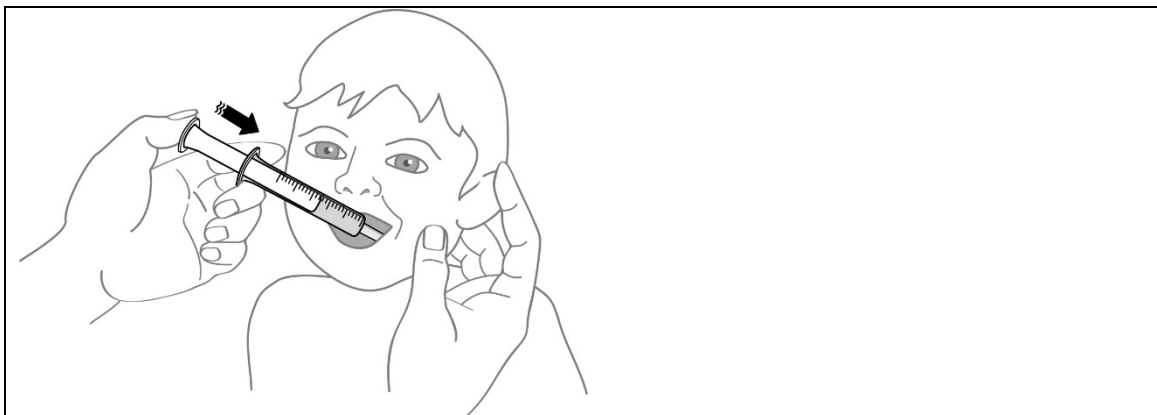
For each dose of EMEND, you will get a pre-filled oral dispenser that contains the child's prescribed dose.

Keep the oral dispenser in the refrigerator (between 2°C and 8°C) until you give the medicine to the child.



Use this medicine within 2 days of getting the medicine from the healthcare provider.

The medicine can be kept at room temperature (not above 30°C) for up to 3 hours, prior to administration.



The colour of the medicine in the oral dispenser may be different shades of pink (light pink to dark pink). This is normal and the medicine is okay to use.

- Take the cap off the oral dispenser.

- Place the tip of the oral dispenser in the child's mouth along in the inner cheek on either the right or left side.
- Slowly push the plunger all the way down to give all the medicine in the oral dispenser.

If the child could not take the whole dose, call the child's healthcare provider.

When you have finished 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.

How much to give

- The doctor will work out the right dose of powder for oral suspension based on the weight of the child.
- Do not change the dose or stop treatment without first talking to the doctor, pharmacist or nurse.

When to give

Day 1:

- Give this medicine one hour before the start of the chemotherapy session.

Day 2 and Day 3:

- If the child will not have chemotherapy - give this medicine in the morning.
- If the child will have chemotherapy - give this medicine one hour before the start of the chemotherapy session.

EMEND can be given with or without food.

Always give this medicine together with other medicines, to prevent nausea and vomiting. After treatment with EMEND, the doctor may ask the child to continue taking other medicines for preventing nausea and vomiting which may include:

- a corticosteroid - such as dexamethasone and
- a '5-HT₃ antagonist' - such as ondansetron

Check with the doctor, pharmacist or nurse if you are not sure.

If you give more EMEND than you should

Do not give the child more of this medicine than the doctor recommends. If you give the child more than you should, contact the doctor straight away.

If you forget to give EMEND

If the child misses a dose of this medicine, talk to the doctor.

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.

Serious side effects

Stop giving this medicine and see a doctor straight away if you or the child notice any of the following serious side effects – the child may need urgent medical treatment:

- allergic reaction – the signs may include hives, rash, itching, difficulty breathing or swallowing (it is not known how often this happens).

Stop giving this medicine and see a doctor straight away if you notice any of the serious side effects above.

Other side effects

Tell the doctor, pharmacist or nurse if you or the child notice any of the following side effects:

Common: may affect up to 1 in 10 people

- constipation or indigestion,
- headache,
- feeling tired,
- loss of appetite,
- hiccups.
- increased amount of liver enzymes in the blood (shown in tests).

Uncommon: may affect up to 1 in 100 people

- feeling dizzy or sleepy,
- acne, rash,
- feeling anxious,
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind,
- pain or burning when urinating,
- feeling weak, generally feeling unwell,
- hot flushes/reddening of the face or skin,
- fast or irregular heartbeat,
- fever with increased risk of infection, low number of red blood cells (shown in tests).

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

- difficulty thinking, lack of energy, changes in taste,
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on the skin, itchy rash, Stevens-Johnson syndrome or toxic epidermal necrolysis (rare severe skin reactions),
- euphoria (feeling of extreme happiness), feeling confused,
- bacterial infection, fungal infection,
- severe constipation, stomach ulcer, inflamed small intestine and colon, sores in the mouth, bloating,
- urinating more often or passing more urine than normal, sugar or blood in urine,
- chest discomfort, swelling, change in the manner of walking,
- cough, mucus in the back of the throat, throat irritation, sneezing, sore throat,
- eye discharge and itching,
- ringing in the ears,
- muscle spasms, muscle weakness,
- feeling very thirsty,
- slow heartbeat, heart and blood vessel disease,
- low number of white blood cells, low sodium levels in the blood, weight loss.

Reporting of side effects

If the child gets any side effects, talk to the 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 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 EMEND

Keep this medicine out of the sight and reach of children.

Before reconstitution:

Emend will generally be stored by healthcare professionals. The storage details, should you need them, are as follows:

Do not give this medicine to the child after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture.

After reconstitution:

The oral suspension can be kept at room temperature (not above 30°C) for up to 3 hours, prior to administration. It can also be stored refrigerated (between 2°C and 8°C) for up to 72 hours.

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 EMEND contains

- The active substance is aprepitant. Each sachet contains 125 mg of aprepitant. After reconstitution, 1 mL oral suspension contains 25 mg of aprepitant.
- The other ingredients are hydroxypropyl-cellulose (E 463), sodium laurilsulfate, sucrose and lactose (see section 2 under ‘EMEND contains sucrose and lactose’), red iron oxide (E 172) and sodium stearyl fumarate.

What EMEND looks like and contents of the pack

The powder for oral suspension is a pink to light pink powder in a single-use sachet.

Single-use carton

Pack size of one carton contains one sachet, one 1 mL and one 5 mL oral dispenser (polypropylene with silicone o-ring), one cap and one mixing cup (polypropylene).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in Great Britain: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London EC2M 6UR, UK

Marketing Authorisation Holder in UK (Northern Ireland): Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

Manufacturer

Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands

For any information about this medicine, please contact:

Merck Sharp & Dohme (UK) Limited
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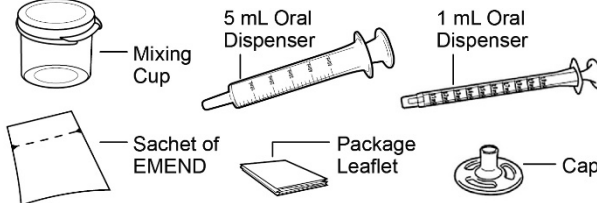

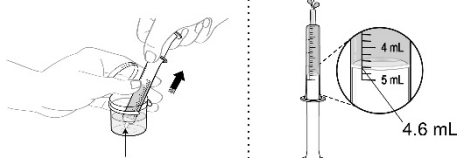
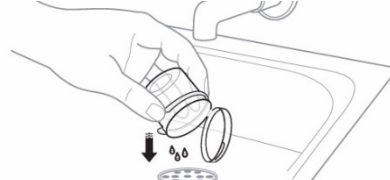

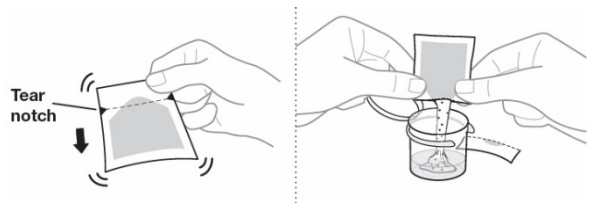
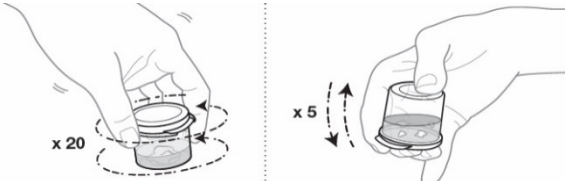
Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

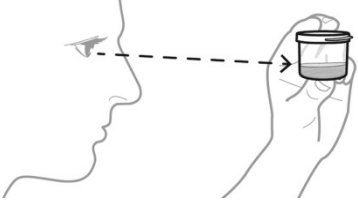

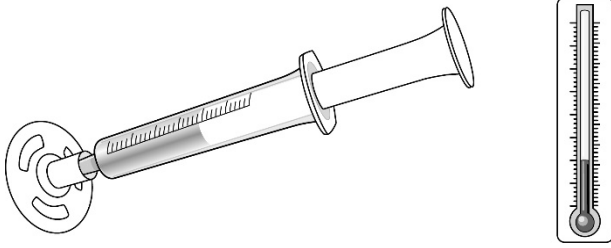
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The following information is intended for healthcare professionals only:

Instructions for healthcare professionals on the preparation of the oral suspension

<p>Each pack of EMEND contains a sachet with the powder for oral suspension, a 1 mL and a 5 mL oral dispenser, one cap and one mixing cup.</p>	
<p>1. Fill the mixing cup with room temperature drinking water.</p>	
<p>2. Fill the 5 mL oral dispenser with 4.6 mL of water from the mixing cup. Make sure no air is in the oral dispenser (if air is present, remove).</p>	
<p>3. Discard all the unused water remaining in the mixing cup.</p>	
<p>4. Add the 4.6 mL of water from the oral dispenser back into the mixing cup.</p>	
<p>5. Each sachet of EMEND for oral suspension contains 125 mg of aprepitant which is to be suspended in 4.6 mL of water giving a final concentration of 25 mg/mL. Hold the EMEND powder for oral suspension sachet upright and shake the contents to the bottom before opening the sachet.</p> <p>6. Pour the entire contents of the sachet into the 4.6 mL of water in the mixing cup and snap the lid shut.</p>	
<p>7. Mix the EMEND suspension gently by swirling 20 times; then gently invert the mixing cup 5 times. To prevent foaming, do not shake the mixing cup. The mixture will be cloudy pink to light pink.</p>	

<p>8. Check the EMEND mixture for any clumps or foaming:</p> <ul style="list-style-type: none"> - If any clumps are present, repeat Step 7 until there are no clumps. - If there is any foam, wait for the foam to disappear before going on to Step 9. 			
<p>9. Fill the oral dispenser with the prescribed dose from the mixing cup according to the table below.</p> <ul style="list-style-type: none"> - Choose the oral dispenser based on dose: <ul style="list-style-type: none"> - Use 1 mL oral dispenser if dose is 1 mL or less. - Use 5 mL oral dispenser if dose is more than 1 mL. - It is common to have medicine leftover in the cup. <p>Make sure no air is in the oral dispenser (if air is present, remove).</p> <p>Make sure the oral dispenser contains the prescribed dose.</p>			
<p>EMEND oral suspension 25 mg/mL</p>	<p>Day 1 3 mg/kg orally Maximum dose 125 mg</p>	<p>Day 2 2 mg/kg orally Maximum dose 80 mg</p>	<p>Day 3 2 mg/kg orally Maximum dose 80 mg</p>
<p>10. Place the cap on the oral dispenser until it clicks.</p> <p>11. If the dose is not administered immediately after measuring, store filled oral dispenser(s) in the refrigerator between 2°C-8°C for up to 72 hours prior to use. When dispensing dose(s) to the caregiver, instruct them to refrigerate the oral dispenser(s) until they are ready to administer the dose.</p> <p>12. The oral suspension can be kept at room temperature (not above 30°C) for up to 3 hours, prior to administration.</p>			
<p>Discard any remaining suspension and waste material. Any unused medicinal product or waste material should be disposed of in accordance with local regulations.</p>			