

Emidol 120mg/5ml

Suspension for babies and infants

Paracetamol BP 120mg/5ml

Please read this leaflet carefully before you start to take your medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for your child and you should not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.
- This medicine brings down high temperatures (also called fever) and relieves pain.
- The medicine is OK for most babies over 2 months and children up to 6 years.
- **Do not give it to children on this list:**
 - Not to babies or children taking some other medicines. See section 2
 - Not to anyone who is allergic to the ingredients. See section 6
- **Follow the dosage instructions carefully.** Children of different ages need different amounts. These are shown in section 3
- **Speak to your doctor** if anything in this list applies:
 - If a child is not getting better, or needs more medicine than shown in section 3
 - If a child gets a rash, breathing problems, diarrhoea or gets very tired. See section 3

In this leaflet:

1. What Emidol suspension is and what it is used for
2. Before giving Emidol suspension
3. How to use Emidol suspension
4. Possible side effects
5. How to store Emidol suspension
6. Further information

1. What is Emidol suspension and what it is used for

The paracetamol in Emidol Suspension is used to relieve pain and / or bring down fever (high temperature) in many conditions including post immunisation fever, teething, headache, cold and flu, toothache, earache, sore throat and other aches and pains.

2 Before giving Emidol Suspension

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not give your child this medicine

- If your child is allergic to paracetamol or any of the other ingredients of this medicines (Listed in section 6).
- If your child has ever had a bad reaction to any of the ingredients.
- If your child is taking anything else with paracetamol in it.
- If your child is between 2-3 months old and is taking this medicine for other causes of pain and fever and:
 - Weighs less than 4 kg or
 - Was born before 37 weeks

If any of these applies, get advice from a doctor or pharmacist without using Emidol.

Warnings and precautions

Talk to your doctor or pharmacist

- If your child has serious kidney or liver problems.
- If your child has an inherited intolerance to fructose or been diagnosed with an intolerance to some other sugars.

Other medicines and Emidol

If your child is taking any other medicines including:

- metoclopramide or domperidone (used to treat nausea and vomiting)
- colestyramine (used to treat high cholesterol)
- anticoagulants (drugs that thin the blood, such as warfarin)
- anticonvulsants (drugs to treat epilepsy)

If you are not sure about the medicine your child is taking, show the bottle or pack to your pharmacist.

If any of these above points apply, talk to a doctor or pharmacist.

If adults take this medicine:

The following additional warnings are included in case an adult takes this product:

- You can use this medicine while you are taking oral contraceptives ("the pill"), but it may not work so well on your pain or fever.
- If you drink large amounts of alcohol, talk to your doctor before you take this medicine. You may be more susceptible to the side-effects of paracetamol.
- Ask your doctor or pharmacist for advice before taking this medicine if you might be pregnant or breast-feeding.

Some of the ingredients can cause problems

- Emidol suspension contains sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to to fructose or some other sugars, contact your doctor before taking this medicinal product.
- Methyl hydroxybenzoate and propyl hydroxybenzoate may cause allergic reactions which could possibly be delayed.
- Sorbitol may have a mild laxative effect. Each 5 ml of this product contains 750mg of sorbitol.
- FD&C red 40 "Allura Red" may cause allergic reaction.
- In high doses, glycerol may sometimes cause headache, stomach upset and diarrhoea.

3. How to use Emidol Suspension

- For oral use only. ■ Always use measured cup supplied with the pack.
- It is important to shake the bottle for at least 10 seconds before use.
- Do not give anything else containing paracetamol while giving this medicine.
- Do not give more medicine than the leaflet tells you to. If your child does not get better, talk to your doctor.

Babies under 2 months

Do not give to babies under 2 months old. Consult your doctor.

Babies 2 - 3 months

For the relief of fever after vaccinations

at 2, 3 and 4 months - 2.5 ml. This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

Pain and other causes of fever

- 2-3 months: 2.5 ml (If necessary, after 4-6 hours, give a second 2.5 ml dose.)
- Do not give to babies less than 2 months of age.
- Only give if your baby weighs over 4 kg and was born after 37 weeks.

- Leave at least 4 hours between doses.
- Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.
- **Children from 3 months to 6 years**
 - 3-6 months: 2.5 ml (up to 4 times in 24 hours)
 - 6-24 months: 5 ml (up to 4 times in 24 hours)
 - 2-4 years: 7.5 ml (up to 4 times in 24 hours)
 - 4-6 years: 10 ml (up to 4 times in 24 hours)
- Do not give more than 4 doses in any 24 hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

Children over 6 years

Ask a pharmacist to recommend a suitable product.

Speak to your doctor:

- If your child needs more than the doses shown above, or if fever doesn't go away, speak to your doctor as soon as possible.
- If you are not sure of the cause of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness or lethargy, speak to your doctor straight away. Do not give Emidol until you get medical advice.

If anyone has too much

Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage. The symptoms of overdose may include pale skin, nausea, sweating, feeling of discomfort or uneasiness, vomiting, loss of appetite and abdominal pain.

If you forget to give the medicine

Give the next dose when needed, provided that the last dose was given at least 4 hours ago. Do not give a double dose.

4 Possible side-effects

Emidol Suspension can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

Tell your doctor as soon as possible if you notice any of these:

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
 - becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking paracetamol.
 - very rare cases of serious skin reactions have been reported (e.g. Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGFP)). Symptoms may include: skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.
- If your child shows any of these signs, stop giving Emidol and talk to a doctor right away.

Long term use: Emidol is NOT intended for long term use.

People who use medicines containing paracetamol every day for a long time (several months or more) could get certain side-effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Emidol Suspension

Keep all medicines out of the sight and reach of children.
Do not store above 30°C. Store in a dry place. Protect from light.
After opening, this product can be used for 30 days, if stored at prescribed storage condition. This product should not be refrigerated.
Do not use Emidol after the expiry date which is stated on the carton and label after {EXP}. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What's in this medicine?

The active ingredient is: Paracetamol BP 120 mg /5 ml.
Other ingredients are: Sucrose, methyl hydroxybenzoate, propyl hydroxybenzoate, xanthan gum, colloidal anhydrous silica, Microcrystalline cellulose, sorbitol solution (70%) non-crystallizing, glycerol, FD&C red 40 "Allura Red", citric acid monohydrate, sodium citrate, strawberry flavor.

What this medicine looks like and contents of the pack

Emidol Suspension is pink to slightly red colored, strawberry flavored homogeneous oral suspension.

Emidol suspension is available in 100 ml amber glass bottle capped with a white colored cap (Child Resistant Cap), provided with a marked measuring cup in a printed carton along with a leaflet.

Marketing Authorisation Holder and Manufacturer

Globalpharma Co. LLC, P. O. Box 72168, Dubai, UAE
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This leaflet was last updated in December 2016 (01-18)

How can you obtain more information about Emidol?

This leaflet does not contain all the information about Emidol. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

To report any side effects:

- **Saudi Arabia:** The National Pharmacovigilance and Drug Safety Centre(NPC).
Fax: +966-11-205-7662 Call NPC at +966-11-2038222,
Exts 2317-2356-2353-2354-2334-2340. Toll free phone: 8002490000 ,
E-mail: npc.drug@sdfa.gov.sa , Website: www.sdfa.gov.sa/npc
- **Other GCC States:** Please contact the relevant competent authority

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENTS OUT OF THE REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacist

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