

INFORMATION FOR THE USER



Pain Reliever, Fever Reducer
Alcohol-Free Syrup

Paracetamol 120mg/5mL

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

What is in this leaflet:

1. What **adol** is and what it is used for
2. Before you give **adol** to your child
3. How to give **adol** to your child
4. Possible side effects
5. How to store **adol**
6. Further information

1. **What **adol** is and what it is used for**
adol used to relieve mild to moderate pain and to reduce fever in many conditions including headache, toothache, teething, feverishness, colds and influenza and following vaccination.

2. **Before you give **adol** to your child**

Do not give **adol to the child:**

- If the child is allergic to **paracetamol** or any of the ingredients listed in section 6.
- If the child has a known intolerance to the sugar
- **"This product contains paracetamol. Severe or possibly fatal liver damage may occur if you take more than the recommended dose in 24 hours or with other drugs containing paracetamol."**
- **"DO NOT USE with other drugs containing paracetamol. If you are not sure whether a drug contains paracetamol, ask a doctor or pharmacist."**

Take special care with **adol**

Please see the doctor before you give **adol** to the child if:

- The child suffers from liver or kidney problems.
- The child is underweight or malnourished.
- The baby was born prematurely.
- The child has a severe infections as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
 - Deep, rapid, difficult breathing
 - Feeling sick (nausea), being sick (vomiting)
 - Loss of appetite

Contact a doctor immediately if the child gets a combination of these symptoms.

Taking other medicines

Please see the doctor before you give **adol** to the child if:

- The child is taking metoclopramide or domperidone (used to treat nausea and vomiting) or cholestyramine (used to treat high cholesterol).
- The child is taking warfarin or other drugs used to prevent blood clotting.
- The child is taking any prescribed drugs or is under the care of a doctor.

Please tell the doctor or pharmacist if your baby is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

If necessary, **adol** can be used during pregnancy.

You should use the lowest possible dose for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced. You can take this product whilst breastfeeding.

Important information of some ingredients of **adol**

If the child has a known intolerance to some sugars, contact the doctor before use as this product contains sorbitol, sucrose and saccharin.

3. **How to give **adol** to your child**

Check the table below to see how much of the medicine to use.

- For oral use only.
- Never give more medicine than shown in the table.
- Always use the measuring cap supplied with the pack.
- Do not overfill the measuring cap.
- If symptoms do not improve within 24 hours consult the doctor.
- Prolonged use except under medical supervision may be harmful.
- This product should only be used when clearly necessary.

Children aged 2 years to under 12 years

Age (years)	Body weight (Kg)	Maximum Single Dose		Maximum daily dose	
		mg	24mg/mL	mg	24mg/mL
2-3	11 – 15.9	160	6.6 mL	800	33.3 mL
4 - 5	16 – 21.9	240	10 mL	1200	50 mL
6 – 8	22 – 26.9	320	13.3 mL	1600	66.6 mL
9-10	27 – 31.9	400	16.6 mL	2000	83.3 mL
11 to under 12	32 – 43.9	480	20 mL	2400	100 mL



Children aged below 2 years.

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Age (months)	Body weight (Kg)	Maximum Single Dose		Maximum daily dose	
		mg	24mg/mL	mg	24mg/mL
0-3	2.7 – 5.4	40	1.6 mL	200	8.3 mL
4 - 11	5.5 – 7.9	80	3.3 mL	400	16.6 mL
12 – 23	8 – 10.9	120	5 mL	600	25 mL

- Seek medical advice before giving to preterm neonate or term neonates <10 days.
- Repeat 4 – 6 hourly up to 5 times per day if required. No more than 5 doses in any 24-hour period.
- Should not be used for more than 5 days for children <2 years) except on medical advice.
- Should not be used with other paracetamol-containing products.
- Do not exceed the stated dose.

If you give too much to the child

Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage.

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

4. Possible side effects

Like all medicines, **adol** can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop using this medicine and tell your doctor immediately if:

Very rare (affects less than 1 in 10,000 people)

- the child experiences allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- the child experiences a skin rash or peeling, or mouth ulcers.
- the child has previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experiences a similar reaction with this product.
- the child experiences unexpected bruising or bleeding.
- the child experiences changes in blood tests that measure the function of their liver.

Other side effects may include a severe reduction in white blood cells which makes infections more likely.

If any of the symptoms become troublesome or if you notice anything else not mentioned here, please contact the doctor or pharmacist.

To report any side effect(s):

- Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Fax: +966-11-205-7662

Call NPC at +966-11-2038222,

Exts: 2317-2356-2340

Reporting Hotline: 19999

E-mail: npc.drug@sfd.a.gov.sa

Website: www.sfd.a.gov.sa/npc

- Other GCC States: Please contact the relevant competent authority.

5. **How to store **adol****

- Keep this medicine out of the reach and sight of children.
- Store below 30°C, in the original container. After opening, use within one month.
- Do not give **adol** after the expiry date which is stated on the carton and inner label. The expiry date refers to the last day of that month.
- Do not give **adol** if you notice any visible sign of deterioration.
- 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 **adol contains**

The active substance is paracetamol.

Each teaspoonful (5mL) of the syrup contains 120mg of paracetamol.

Other ingredients: Sucrose, sorbitol, propylene glycol, glycerin, sodium saccharin, polyvinyl pyrrolidone, vanillin, raspberry flavor, raspberry red color, sodium citrate, citric acid monohydrate and purified water.

What are the available packs of **adol**

adol syrup is available in packs of one bottle (60mL or 100mL) each, with measuring cap.

THIS IS A MEDICATION

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicines their 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 all medications out of reach of the children.

Council of Arab Health Ministers,
Union of Arab Pharmacists

Any information? Call (971) 800-4994, U.A.E.



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