

## Package leaflet: Information for the user

### FOR RECTAL ADMINISTRATION ONLY

## Alvedon<sup>®</sup> Suppositories 60 mg paracetamol

**Read all of this leaflet carefully before you give this medicine to your child because it contains important information for your child.**

Always use this medicine exactly as described in this leaflet or as your child's doctor or pharmacist has told you.

This medicine is available without prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your child does not feel better or if your child feels worse.

### **What is in this leaflet:**

1. What Alvedon Suppositories are and what they are used for
2. What you need to know before you give Alvedon Suppositories to your child
3. How to give Alvedon Suppositories to your child
4. Possible side effects
5. How to store Alvedon Suppositories
6. Contents of the pack and other information

## **1. What Alvedon Suppositories are and what they are used for**

A suppository is a small, cone-shaped medicine which is inserted into the back passage (rectum).

Alvedon Suppositories contain a medicine called paracetamol. This belongs to a group of medicines called pain-killers (analgesics).

Alvedon Suppositories are used to treat pain and high temperature (fever) in children up to the age of 1 year. They are used by children who find it difficult to take paracetamol as tablets or syrup.

## **2. What you need to know before you give Alvedon Suppositories to your child**

### **Do not give Alvedon Suppositories to your child:**

- if they are allergic to paracetamol or to the other ingredient of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your child's doctor or pharmacist before using these suppositories:

- if your child has liver or kidney problems.

- if your child is taking other medicines which can affect their liver (see ‘Other medicines and Alvedon Suppositories’ section).
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

### **Other medicines and Alvedon Suppositories**

Tell your child’s doctor or pharmacist if your child is taking, has recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Alvedon Suppositories can affect the way some medicines work and some medicines can have an effect on Alvedon Suppositories.

In particular, tell your child’s doctor or pharmacist if your child is taking any of the following:

- Other medicines that contain paracetamol – **do not give your child Alvedon Suppositories at the same time.**
- Barbiturates (a type of sedative).
- Medicines for epilepsy or fits (also called ‘anti-convulsants’).
- Medicines such as warfarin for treating blood clots.
- Chloramphenicol (a medicine used to treat bacterial infections).
- Probenecid (a medicine used to prevent gout and, occasionally, to increase blood levels of the antibiotic penicillin).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

### **Alvedon Suppositories with alcohol**

Do not give your child alcohol, or any medicines containing alcohol, while they are being given these suppositories.

## **3. How to give Alvedon Suppositories to your child**

Always give this medicine to your child exactly as described in this leaflet or as your child’s doctor or pharmacist has told you. Check with your child’s doctor or pharmacist if you are not sure.

Alvedon Suppositories 60 mg are for children aged up to 1 year. Higher strengths of Alvedon Suppositories are available for children above 1 year of age.

### **Use in children aged 3 months to 1 year**

- The number of suppositories to give your child depends on their age and weight.
- The recommended dose is one or two suppositories.
- You should ask your child’s doctor or pharmacist for advice on how many suppositories to give.
- You can give your child up to 4 doses in 24 hours. You must leave at least 4 hours between each dose.

### Use in infants under 3 months

- One suppository can be given to babies who develop a fever after immunisation at 2 months.
- Otherwise do not give to babies aged less than 3 months unless your doctor advises you to.

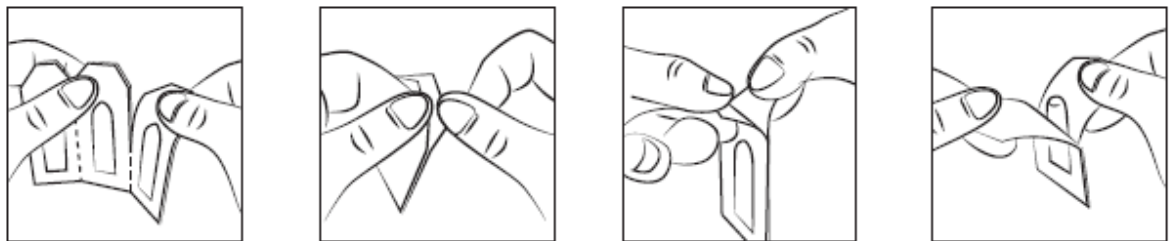
If you are not sure how many suppositories to give your child, **don't guess**. Ask your child's doctor or pharmacist for advice.

### Do not give your child more suppositories than stated above.

Contact your child's doctor if your child's symptoms get worse or do not improve.

### How to use Alvedon Suppositories

1. Your child's bowels need to be empty when you give them this medicine. If your child needs to go to the toilet, make sure that they do it before you give them the suppository.
2. You may find it easier to give your child the suppository if they are lying on their front or side on a bed. Do whichever is more comfortable for your child.
3. Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.



4. Gently push the suppository into your child's back passage (rectum) with the pointed end first. Then wash your hands.
5. Try to keep your child still for a minute or two.
6. If your child needs to be given another suppository, remove another one from the wrapper. Then insert it into your child's back passage as before. Once again you should try to keep your child still for a minute or two. Then wash your hands.

### If you give more Alvedon Suppositories to your child than you should

- Do not give your child more suppositories than stated overleaf (in the sections called "Use in children aged 3 months to 1 year" and "Use in infants under 3 months").
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage. Your child may need to have a blood test to check how well their liver is working.

### If you forget to give Alvedon Suppositories to your child

- If you forget to give your child a dose of Alvedon Suppositories, give it to them as soon as you remember.
- However, if it is almost time for the next dose, skip the missed dose.
- **Do not give your child a double dose (two doses at the same time) to make up for a forgotten dose.**

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects can happen with this medicine.

##### **Common (may affect up to 1 in 10 people)**

- Redness or soreness in or around the back passage.

##### **Rare (may affect up to 1 in 1,000 people)**

- Allergic reactions such as swelling of the face, lips, tongue or throat.
- Skin problems such as a rash or itching.
- Blood problems. If these happen, your child may bruise or bleed more easily, get infections more easily, or get a high temperature (fever) and ulcers in the mouth and throat.
- Liver problems (your child may need to have blood tests to check how well their liver is working).

##### **Not known (frequency cannot be estimated from the available data)**

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Very rare cases of serious skin reactions have been reported.

#### **Reporting of side effects**

If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Alvedon Suppositories**

- 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. The expiry date refers to the last day of that month.
- Store this medicine in a cool, dry place (below 25°C) and out of direct sunlight.
- Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment. Ask your pharmacist how to throw away medicines you no longer use, unless your child's doctor has told you to keep them.

#### **6. Contents of the pack and other information**

##### **What Alvedon Suppositories contain**

The active substance is paracetamol. Each suppository contains 60 mg of paracetamol. The other ingredient is hard fat (Witepsol H12).

##### **What Alvedon Suppositories look like and contents of the pack**

Alvedon Suppositories are cone-shaped and come in packs of 5 or 10. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Manufacturer**

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