

Product:	Paracetamol 120mg/5ml Elixir	Printing Colours:	Non-Printing Colours:	APL
MA Holder:	Activase	Black	Profile	
PL No.:	28444/0068	Dimensions:	384 x 60 mm	Final Preparation Date For Submission: 17/03/2025
Pack Size:	All Pack	AW Code:	A0068/P/LL/A2	Packing Site Technical Approval:
Livery:	Activase	Bar Code:	-	00/00/0000
Manufacturer:	-	Font & Size:	Arial Regular, 7 pt	Authority Approval Date: 00/00/0000
Market:	UK	Created By:	[REDACTED]	Latest Implementation Deadline: 00/00/0000
Component:	Label Leaflet	Version:	0.1	Print Proof Approval:
				00/00/0000

Prompt list for artwork checks

- Are the dimensions correct?
- Are the font sizes correct?
- Are the livery and colours correct?
- Is the content (text) correct?
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<p>PACKAGE LEAFLET: INFORMATION FOR THE USER</p> <p>Paracetamol 120mg/5ml Elixir</p> <p>Read all of this leaflet carefully because it contains important information for you.</p> <p>This medicine is available without prescription. However, you still need to take Paracetamol Elixir carefully to get the best results from it.</p> <ul style="list-style-type: none"> Keep this leaflet. You may need to read it again Ask your pharmacist if you need more information or advice You must contact a doctor if your symptoms worsen or do not improve If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist. 	<p>In this leaflet:</p> <ol style="list-style-type: none"> What Paracetamol Elixir is and what it is used for Before you give Paracetamol Elixir How to give Paracetamol Elixir Possible side effects How to store Paracetamol Elixir Further information <p>1. WHAT PARACETAMOL ELIXIR IS AND WHAT IT IS USED FOR</p> <p>Paracetamol Elixir contains the active ingredient Paracetamol and is used to treat mild to moderate pain in children, including:</p> <ul style="list-style-type: none"> Aches and pains Neuralgia (severe nerve pain), period pain Migraine, headache Fevers, colds, flu and influenza Sore throat, toothache, pain in teething 	<p>2. BEFORE YOU GIVE PARACETAMOL ELIXIR</p> <p>DO NOT give your child Paracetamol Elixir if he/she is:</p> <ul style="list-style-type: none"> Allergic (hypersensitive) to Paracetamol, other pain relievers or any of the other ingredients in the product (see Section 6 and end of Section 2). Taking any other Paracetamol-containing medicines, i.e. over-the-counter cold remedies. <p>Warning and Precautions</p> <p>During treatment with Paracetamol Elixir, tell your doctor straight away if:</p> <p>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</p>	<p>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).</p> <p>Take special care with Paracetamol Elixir</p> <p>Consult the doctor before giving this medicine to your child if he/she has impaired kidney or liver function.</p> <p>Taking other medicines</p> <p>Please tell the doctor if your child is taking, or has recently taken, any other medicines, including those obtained without a prescription, particularly:</p> <ul style="list-style-type: none"> Other products containing Paracetamol (see 'DO NOT give your child Paracetamol Elixir' above). Medication for the liver Metoclopramide and Domperidone (used to treat nausea, vomiting or other stomach problems). 	<ul style="list-style-type: none"> Cholestyramine (reduces blood cholesterol levels) Warfarin and other drugs which thin the blood Drugs for epilepsy i.e. Phenytoin, Phenobarbital, Carbamazepine Rifampicin (antibiotic most frequently used to treat tuberculosis) St. John's wort (used to treat depression) Alcohol-containing products flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2). <p>Important information about some of the ingredients of Paracetamol Elixir</p> <ul style="list-style-type: none"> Alcohol – this medicinal product contains 8.4% vol of ethanol (alcohol), i.e. up to 421mg per dose, equivalent to 8.4ml of beer, 3.5ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in children and high-risk groups such as patients with liver disease, or epilepsy. 	<ul style="list-style-type: none"> Propylene Glycol – may cause alcohol like symptoms Sorbitol – when taken according to the dosage recommendation each dose supplies up to 6.9g of Sorbitol. If your child has an intolerance to some sugars like fructose, ask the doctor before giving this medicine. Sorbitol may have a mild laxative effect. Amaranth – may cause allergic reactions. Glycerol – may cause headache, stomach upset and diarrhoea. <p>3. HOW TO GIVE PARACETAMOL ELIXIR</p> <p>Always give Paracetamol Elixir exactly as the doctor has told you. For oral use only.</p> <p>Check the table below to see how much of the medicine to use</p> <ul style="list-style-type: none"> For oral use only It is important to shake the bottle for at least 10 seconds before use
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- Never give more medicine than shown in the table
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give this medicine with any other paracetamol-containing product

Children:

Child's Age	How Much	How often (in 24 hours)
3 – 6 months	One 2.5 mL spoonful (small end)	4 times
6 – 24 months	One 5 mL spoonful (large end)	4 times
2 – 4 years	One 5.0 mL spoonful (large end) and one 2.5mL spoonful (small end)	4 times
4 – 8 years	Two 5 mL spoonfuls (large end)	4 times
8 – 10 years	Three 5 mL spoonfuls (large end)	4 times
10 – 12 years	Four 5 mL spoonfuls (large end)	4 times

- 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 days without speaking to your doctor or pharmacist

WARNING: DO NOT EXCEED THE STATED DOSE

Contains Paracetamol. Do not give with other Paracetamol containing products.

If you give more Paracetamol Elixir than you should It is extremely important to follow the dosage instructions that have been given. Do not change the dose without discussing it with the doctor first.

Symptoms of overdose include pallor (paleness of skin), nausea, vomiting, anorexia and stomach pain. If your child accidentally takes more than the recommended dose, contact their doctor or nearest hospital casualty immediately. Take any remaining medicine and this leaflet with you if possible.

IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSE, EVEN IF YOUR CHILD FEELS WELL, BECAUSE OF THE RISK OF DELAYED, SERIOUS LIVER DAMAGE.

If you forget to give Paracetamol Elixir

If your child misses a dose, give it as soon as you remember. NEVER give a double dose to make up for the dose that has been forgotten.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol Elixir can cause side effects, although not everybody gets them. **Your child may suffer an allergic reaction, symptoms of which include skin rashes and itching. If this happens, stop giving the medicine immediately and seek urgent medical help.**

The following have also been reported:

- Blood abnormalities, but these were not necessarily due to the Paracetamol treatment.
- Kidney disorders

Frequency “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)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell the doctor.

5. HOW TO STORE PARACETAMOL ELIXIR

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original container and keep the bottle tightly closed. Do not use Paracetamol Elixir after the expiry date shown.

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 Paracetamol Elixir contains

The **active** substance is Paracetamol, 120mg per 5ml of Elixir. The **other** ingredients are Alcohol 96% (Ethanol 8.4% w/v), Propylene Glycol, Potassium Sorbate (E202), Sorbitol (E420), Glycerol (E422),

Saccharin Sodium, Raspberry Flavour (IFF 17.40.0478), Citric Acid Hydrated (E330), Amaranth Ariavit 311801 (E123), Purified Water (see also end of Section 2 on 'Important information about some of the ingredients of Paracetamol Elixir').

What Paracetamol Elixir looks like and contents of the pack

This medicine is a clear red oral solution with raspberry flavouring. It is supplied in an amber glass bottle in packs of 60ml, 100ml and 200ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Activase Pharmaceuticals Limited,
11 Boumpoulinas Street, 1060 Nicosia, Cyprus

Manufacturer:

DDSA Pharmaceuticals Limited,
310 Old Brompton Road, London, SW5 9JQ

Date of last revision: 03/2025

A0068/P/LL/A2

Please read the Package Leaflet on the reverse of this label before use.

HOW MUCH TO GIVE

NEVER GIVE MORE MEDICINE THAN SHOWN IN THE TABLE

As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist, before taking this product.

Child's Age	New Dosage	How often (24 hours)
3 – 6 months	One 2.5 mL spoonful (small end)	4 times
6 – 24 months	One 5 mL spoonful (large end)	4 times
2 – 4 years	One 5.0 mL spoonful (large end) and one 2.5mL spoonful (small end)	4 times
4 – 8 years	Two 5 mL spoonfuls (large end)	4 times
8 – 10 years	Three 5 mL spoonfuls (large end)	4 times
10 – 12 years	Four 5 mL spoonfuls (large end)	4 times

- 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

CONTAINS PARACETAMOL – Do not give this medicine with any other Paracetamol-containing products.

IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSE, EVEN IF THE CHILD SEEMS WELL.

DO NOT STORE ABOVE 25°C. KEEP THE BOTTLE TIGHTLY CLOSED. STORE IN THE ORIGINAL PACKAGE.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN