



Ursodeoxycholic acid for cholestasis and sclerosing cholangitis



This leaflet is for parents and carers about how to use this medicine in children. Our information may differ from that provided by the manufacturers, because their information usually relates to adults. Read this leaflet carefully. Keep it somewhere safe so that you can read it again.

Name of medicine

Ursodeoxycholic acid

Brand names: Destolit[®], Chlorursol, Ursofalk[®], Ursogal[®]

Why is it important to take this medicine?

Bile is made in the liver and flows through a tube (the bile duct) to the intestines, where it helps to break down fat in food. In cholestasis and sclerosing cholangitis, the bile duct becomes blocked so less bile reaches the intestines; this can also damage the liver. Ursodeoxycholic acid will improve the flow of bile and help your child to digest fat properly.

What is ursodeoxycholic acid available as?

- **Tablets:** 150 mg, 300 mg, 500 mg; contain lactose
- **Capsules:** 250 mg; contain gelatin
- **Liquid medicine:** 250 mg in 5 mL; contains propylene glycol


When should I give ursodeoxycholic acid?

Ursodeoxycholic acid is usually given either **two or three times** a day.

- **If giving twice a day.** Give one dose in the morning and one in the evening. Ideally these times are 10–12 hours apart. For example, this could be between 7 am and 8 am and between 7 pm and 8 pm.
- **If giving three times a day.** The doses should be evenly spaced, usually 4–6 hours apart. For example, between 7 am and 8 am, between 1 pm and 2 pm, and between 7 pm and 8 pm.

How much should I give?

Your doctor will work out the amount of ursodeoxycholic acid (the dose) that is right for *your* child. The dose will be shown on the medicine label.

 **It is important that you follow your doctor's instructions about how much to give.**

How should I give it?

Ursodeoxycholic acid should be taken with or after food.



Tablets should be swallowed with a glass of water, juice or squash. Your child should not chew the tablet.

You can crush the tablet and mix it with a small amount of soft food such as yogurt or jam. Make sure your child swallows it straight away, without chewing.



Capsules should be swallowed with a glass of water, juice or squash. Your child should not chew the capsule. You can open the capsules and mix the contents with a small amount of soft food such as yogurt or jam. Make sure your child swallows it straight away, without chewing.



Liquid medicine: Shake the bottle well and measure out the right amount using an oral syringe or medicine spoon. You can get these from your pharmacist. Do not use a kitchen teaspoon as it will not give the right amount.

When should the medicine start working?

The medicine should start working after about 2–3 days, although you will not see any difference in your child.

What if my child is sick (vomits)?

- If your child is sick less than 30 minutes after having a dose of ursodeoxycholic acid, give them the same dose again.
- If your child is sick more than 30 minutes after having a dose of ursodeoxycholic acid you **do not** need to give them another dose. Wait until the next normal dose.

If your child is sick again, seek advice from your doctor, pharmacist or hospital.

What if I forget to give it?

If you usually give it twice a day: If you remember up to 4 hours after you should have given a dose, give your child the missed dose. For example, if you usually give a dose at about 7 am, you can give the missed dose at any time up to 11 am. If you remember after that time, do not give the missed dose. Give the next dose as usual.

If you usually give it three times a day: Do not give the missed dose. Just give the next dose as usual.

What if I give too much?


You are unlikely to do harm if you give an extra dose of ursodeoxycholic acid by mistake.

If you are concerned that you may have given too much, contact your doctor or local NHS services (details at end of leaflet). Have the medicine or packaging with you if you telephone for advice.

Are there any possible side-effects?

We use medicines to help our children, but sometimes they have effects that we don't want (side-effects).

Side-effects you must do something about

 If your child is short of breath or is wheezing, or their face, lips or tongue start to swell, or they develop a rash, they may be allergic to ursodeoxycholic acid. Take your child to hospital or call an ambulance **straight away**.

Other side-effects you need to know about

- Your child may have loose stools (poo) or diarrhoea (runny poo), but this is very rare. Encourage your child to drink plenty of water to replace the fluid they have lost. If diarrhoea is severe and watery, or if it is still a problem after 2 weeks, contact your doctor.

Your child may sometimes get side-effects that are not listed above. Contact your doctor if you notice anything unusual or are concerned. You can report suspected side-effects to www.mhra.gov.uk/yellowcard.

Can other medicines be given at the same time as ursodeoxycholic acid?

- You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to.
- Ursodeoxycholic acid should not be taken at the same time as some medicines, such as some antacids and other treatments for indigestion. Tell your doctor or pharmacist about any other medicines your child is taking **before** giving ursodeoxycholic acid.
- Check with your doctor or pharmacist **before** giving any other medicines to your child. This includes herbal and complementary medicines.

Is there anything else I need to know about this medicine?

- Ursodeoxycholic acid should not be taken at the same time as some antacid or indigestion treatments. Check with your doctor or pharmacist before using these.

General advice about medicines

- Try to give medicines at about the same times each day, to help you remember.
- If you are not sure a medicine is working, contact your doctor but continue to give the medicine as usual. Do not give extra doses, as you may do harm.
- Only give ursodeoxycholic acid to your child. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- If you think someone else may have taken the medicine by accident, contact your doctor.

- Make sure that you always have enough medicine. Order a new prescription at least 2 weeks before you will run out.
- Make sure that the medicine you have at home has not reached the 'use by' date on the packaging. Give old medicines to your pharmacist to dispose of.

Where should I keep this medicine?

- Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge.
- The liquid medicine does not keep for long once opened. Write down the date that you start it on the bottle and do not keep it for longer than stated on the label.
- Make sure that children cannot see or reach the medicine.
- Keep the medicine in the container it came in.

Who to contact for more information

Your child's doctor, pharmacist or nurse will be able to give you more information about ursodeoxycholic acid and about other medicines used to treat cholestasis and sclerosing cholangitis.

You can also get useful information from:

England: NHS 111

Tel 111
www.nhs.uk

Scotland: NHS 24

Tel 111
www.nhs24.scot

Wales: NHS Direct

Tel 0845 46 47 (2p per minute) or 111 (free)
www.nhsdirect.wales.nhs.uk

Northern Ireland: NI Direct

www.nidirect.gov.uk

www.medicinesforchildren.org.uk



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The primary source for the information in this leaflet is the British National Formulary for Children. For details on any other sources used for this leaflet, please contact us through our website, www.medicinesforchildren.org.uk

We take great care to make sure that the information in this leaflet is correct and up-to-date. However, medicines can be used in different ways for different patients. It is important that you ask the advice of your doctor or pharmacist if you are not sure about something. This leaflet is about the use of these medicines in the UK, and may not apply to other countries. The Royal College of Paediatrics and Child Health (RCPCH), the Neonatal and Paediatric Pharmacists Group (NPPG), WellChild and the contributors and editors cannot be held responsible for the accuracy of information, omissions of information, or any actions that may be taken as a consequence of reading this leaflet.