This leaflet has been written specifically about the use of this medicine in children. The information may differ from that provided by the manufacturer. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.

**Name of drug**
Ursodeoxycholic acid

**Brand names:** Destolit®, Urdox®, 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 the bile cannot reach the food very well; 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; these contain small amounts of lactose
- **Capsules:** 250 mg
- **Liquid medicine:** 250 mg in 5 mL; this contains propylene glycol

**When should I give ursodeoxycholic acid?**
- Ursodeoxycholic acid is usually given three times a day. This should be in the morning, early afternoon and at bedtime. Ideally, these times are at least 6 hours apart, for example 8 am, 2 pm and 8 pm.
- Ursodeoxycholic acid should be taken with or after food.

**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?**
- **Tablets:** should be swallowed with a glass of water, milk or juice. 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, honey or jam. Make sure your child swallows it straight away, without chewing.

**Capsules** should be swallowed with a glass of water, milk or juice. Your child should not chew the capsule. You can open the capsules and mix the contents with a small amount of food such as yogurt, honey 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.

**What if I forget to give it?**
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 NHS Direct (0845 46 47 in England and Wales; 08454 24 24 24 in Scotland). Have the medicine or packaging with you if you telephone for advice.

**Are there any possible side-effects?**
We use medicines to make our children better, but sometimes they have other effects that we don’t want (side-effects).

**Side-effects you must do something about**
If your child develops blistering of the skin or any other skin reactions, they may be allergic to ursodeoxycholic acid. Contact your doctor or take your child to hospital 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 two weeks, contact your doctor.

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 with some common drugs that you get on prescription, such as some antacid or indigestion treatments. It is important to tell your doctor and pharmacist that your child is taking ursodeoxycholic acid.

• Check with your doctor or pharmacist before giving any other medicines to your child. This includes herbal or complementary medicines.

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

• Ursodeoxycholic acid should be taken with or after food.

• Ursodeoxycholic acid should not be taken with some antacid or indigestion treatments. Check with your 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 in the meantime. 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 ‘best before’ or ‘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.

• 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:

NHS Direct (England)
www.nhsdirect.nhs.uk- 0845 46 47

NHS 24 (Scotland)

NHS Direct Wales/Galw lechyd Cymru
www.nhsdirect.wales.nhs.uk - 0845 46 47

NI Direct (Northern Ireland)
www nidirect.gov.uk