



ISOTRETINOIN

Information for families

This information sheet from Great Ormond Street Hospital (GOSH) describes how this medicine is given and some of its possible side effects. Each person reacts differently to medicines so your child will not necessarily experience every side effect mentioned. If you have any questions or concerns, please ask your doctor, nurse or pharmacist or telephone one of the contact numbers of this information sheet.

What is it for?

Isotretinoin is a retinoid, which is a type of Vitamin A. It is commonly used for the treatment of severe acne. Retinoids are thought to influence the way in which cells grow, develop, and prevent the production of specific genes that may cause cancer.

It is known to be effective in the treatment of a number of different types of cancer. It has been shown to improve survival in patients with high risk or Stage M neuroblastoma.

Isotretinoin is also called 13-cis-retinoic acid, which is available as 10mg and 20mg capsules and 20mg/ml oral liquid.

This course is usually repeated and may be given in conjunction with other treatments. Giving the treatment in this way has been shown to be the best way to achieve maximum effect with the minimum of side effects.

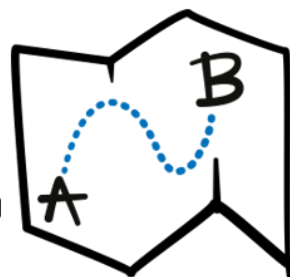
Important information about the Liquid formulation

The liquid is flavoured with tutti-frutti flavour. The liquid medicine is ordered specially for each patient. The liquid medicines must be kept away from all sources of light. When you are giving the medicine to your child, limit the amount of time the bottle is exposed to light and keep the bottle in its original box. It is very important to shake the liquid in the bottle before each dose. If administering down an NG tube or PEG tube, flush the NG tube with olive oil after administering the isotretinoin and then flush as normal with water.

How is it given?

It is given by mouth as a capsule or liquid. The liquid can administered down an NG tube or PEG tube. You should give one dose to your child twice a day for 14 days in a row. Your doctor or pharmacist will tell you how many capsules or how much liquid to give.

Soya allergy - Isotretinoin capsules contain soya. If your child is allergic to soya, he or she should not take isotretinoin capsules (liquid is fine). Please tell your doctor who will be able to discuss possible alternative treatment with you.



What are the side-effects?

Side effects are uncommon, but Isotretinoin can cause:

- **Drying of skin, lips, and eyes:** Moisturisers and lip salves containing vitamin E should be used during treatment (applied a minimum of 4-6 times a day) with isotretinoin, ideally even before the skin and lips become cracked and dry. If your child develops dry/cracked skin or lips you must contact your keyworker or oncology team.
- **Sensitivity to sunlight:** Your child's skin may also become more sensitive to sunlight. Your child should avoid being exposed to sunlight and other forms of ultraviolet light. If they do go out in the sun, always use a good sunblock (SPF 50 or higher and wear a hat).
- **Bone marrow suppression:** There will be a temporary reduction in how well your child's bone marrow works. This is unlikely to have any noticeable effects.
- **Changes in liver function:** Isotretinoin may change how well your child's liver works. These changes may happen rapidly. Blood tests (LFTs) will be taken to monitor your child's liver function during treatment. Please contact your doctor immediately if your child complains of pain in their right side or the whites of their eyes or their skin develops a yellow tinge.
- **Effects on the unborn child:** Isotretinoin must not be given to girls who may be pregnant or are likely to become pregnant in the near future. If your daughter is ten years old or older, we will ask her about her periods and any possibility that she could be pregnant. We will also carry out a pregnancy test on a fresh urine sample. If your daughter is sexually active, she must use a reliable form of contraception.

- **Increase in blood fats:** Isotretinoin can cause raised levels of some fats in the blood (triglycerides). This will not have any noticeable effect. Blood tests will be taken, and doses adjusted if necessary.

If you are concerned about any of these side effects, please discuss them with your doctor or pharmacist.

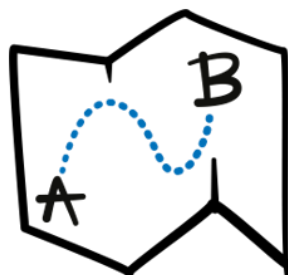
Isotretinoin and other medications

Some medicines can interact with Isotretinoin, altering how well it works.

Always check with your doctor or pharmacist before giving your child any other medicines, including medicines on prescription from your family doctor (GP), medicines bought from a pharmacy (chemist) or any herbal or complementary medicines.

Important

- Keep medicines in a safe place where children cannot reach them.
- Isotretinoin capsules should be kept in a cool, dry place away from direct sunlight or heat.
- Keep the capsules in their original packaging.
- If you forget to give your child a dose and it is within a few hours of when the dose was due, give it as soon as you remember. Otherwise, do not give this dose but wait until the next dose is due. Do not give a double dose.
- If your child vomits straight after taking the dose, inform your doctor or nurse, as your child may need to take another one.
- Do not give your child any other medicines that contain Vitamin A, while they are taking isotretinoin. If you are not sure about other medicines, please ask your pharmacist, doctor, or nurse.
- If your doctor decides to stop treatment with isotretinoin or the medicine passes its expiry date, return any remaining medicine to the pharmacist.
- You cannot get this medicine from your GP or local community pharmacy.



You should handle these medicines with care, avoiding touching the capsules where possible. If you are pregnant or think you could be pregnant, please discuss handling instructions with your doctor, nurse, or pharmacist.

Please see our Special handling requirements information sheet for further details.

Accidental Spillages

- If you accidentally spill the liquid on the work surface or floor, wearing gloves, cover the spillage with kitchen paper. Wipe the area with water then clean with household cleaner and water.
- If the liquid gets onto your skin, you must wash the area immediately, using plenty of water. If the skin is sore, you should contact your GP (family doctor) for advice.
- If the liquid accidentally gets into your eyes, wash with plenty of running water for at least 10 minutes. If your eyes are sore after this, you should go to your nearest Accident and Emergency (A&E) department.
- If the liquid is spilt on clothing, the spill should be blotted dry with kitchen paper. Clothing should be removed immediately and washed separately from other items. Used kitchen paper should be disposed of as above.
- Used paper towels, masks, vomit, and dirty disposable nappies should be placed inside two rubbish bags and disposed of along with your normal rubbish.

If any type of spillage occurs, you should contact GOSH for advice immediately.

For further information please contact:

Medicines Information: 020 7829 8608 or via the Medications page on the MyGOSH app (available Monday – Friday, 9am - 5pm excluding Bank Holidays)

GOSH switchboard: 020 7405 9200 or contact your clinical team directly via the MyGOSH app

Disclaimer

Please read this information sheet from GOSH alongside the patient information leaflet (PIL) provided by the manufacturer. If you do not have a copy of the manufacturer's patient information leaflet please talk to your pharmacist. A few products do not have a marketing authorisation (licence) as a medicine and therefore there is no PIL.

For children in particular, there may be conflicts of information between the manufacturer's patient information leaflet (PIL) and guidance provided by GOSH and other healthcare providers. For example, some manufacturers may recommend, in the patient information leaflet, that a medicine is not given to children aged under 12 years. In most cases, this is because the manufacturer will recruit adults to clinical trials in the first instance and therefore the initial marketing authorisation (licence) only covers adults and older children.

For new medicines, the manufacturer then has to recruit children and newborns into trials (unless the medicine is not going to be used in children and newborns) and subsequently amend the PIL with the approved information. Older medicines may have been used effectively for many years in children without problems but the manufacturer has not been required to collect data and amend the licence. This does not mean that it is unsafe for children and young people to be prescribed such a medicine 'off-licence/off-label'. However, if you are concerned about any conflicts of information, please discuss with your doctor, nurse or pharmacist.

