



METHOTREXATE: 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?

Methotrexate belongs to a group of medicines known as cytotoxic medicines which treat chronic inflammatory conditions such as Juvenile Idiopathic Arthritis, Juvenile Dermatomyositis, Systemic Lupus Erythematosus, Vasculitis, and severe Psoriasis. Methotrexate is also used in the treatment of cancer but at much higher doses.

tablets/syrup or if the inflammation fails to respond to the oral methotrexate.

The dose of methotrexate is calculated on your child's weight so the dose will increase as they grow.

What are the side-effects?

Most side effects are uncommon, but methotrexate can cause:

How is it given?

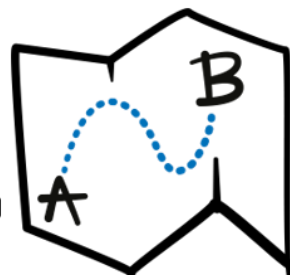
Methotrexate is available as tablets, an oral syrup or as an injection under the skin (subcutaneous) and is given only once a week. It should be given on the same day each week and may take 6 to 12 weeks before a benefit is noticed.

The usual practice is to remain on methotrexate until your child is in remission (no active inflammation) – this may be for several years.

If your child is taking the oral solution, you should use an oral syringe to draw up the correct dose. These instructions will be on the medicine label.

The doctor may suggest changing to injectable methotrexate if your child is unable to tolerate the

- Nausea or stomach upset – This is quite common and is usually managed by taking the dose with or after food. Taking the medicine on Friday nights means that school is not missed if there is some stomach upset the next day. Please speak to your doctor or nurse if nausea or vomiting is becoming a problem.
- Mouth ulcers
- Thinning of the hair – not usually a noticeable problem
- Generally feeling unwell, including fatigue and loss of appetite – we will prescribe folic acid, which can help to prevent or minimise this and other side effects.



- Effects on the blood count – monitored carefully with regular blood tests
- Inflammation of the liver – monitored carefully with regular blood tests. Alcohol should not be taken with methotrexate as it may upset liver function.
- Skin rashes – uncommon
- Cough and breathing problems – incredibly rare in children and young people
- Effects on the unborn child – methotrexate must not be given to patients who may be pregnant or are likely to become pregnant in the near future. If your daughter is over twelve years old, we will ask her about her periods and any possibility that she could be pregnant. If the young person is sexually active, they must use contraception.

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

Who should not take methotrexate (contraindications)?

People with the following conditions should discuss taking methotrexate with their doctor:

- Hypersensitivity to methotrexate or any of its ingredients
- Pregnant, could be pregnant, trying to become pregnant or breastfeeding
- Existing severe blood disorders
- Existing breathing problems
- Existing kidney problems

Methotrexate and other medications

Some medicines can interact with methotrexate.

Always check with your doctor or pharmacist before giving your child any other medicines, including herbal or complementary medicines.

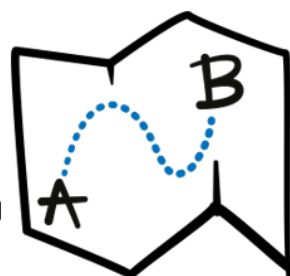
Your child should NOT have any live vaccinations such as inhaled influenza/flu, MMR, oral polio, chicken pox, yellow fever or BCG while taking methotrexate. Inactivated or killed vaccines such as the injectable influenza/flu, meningitis C, pneumococcal, hepatitis, Hib, tetanus, diphtheria, whooping cough/pertussis and the killed version of the polio immunisation are permitted if the patient is stable on treatment.

Regular monitoring

Your child must have regular blood tests every two to eight weeks. Most children do not have any problems but if they do occur, the methotrexate may be briefly stopped or the dose reduced, Children treated with methotrexate will be given a card to record the results of these blood tests.

Important

- Methotrexate should never be given more than once a week.
- Keep medicines in a safe place where children cannot reach them.
- Keep medicines in a cool, dry place out of direct sunlight and away from heat.
- You should handle these drugs with care. Avoid touching the methotrexate wherever possible.
- Methotrexate tablets are made in two strengths – 2.5mg and 10mg. They are different shapes, but a similar colour so always check you have been given the correct strength by your doctor or pharmacist. Do not take the tablets if you think you have the wrong strength. Check with your doctor or pharmacist first.
- Methotrexate is also available in liquid form. It is important to check with your doctor or pharmacist that you are giving the correct volume.
- If your child is being treated with ciclosporin and has not had chicken pox but comes into contact with someone who has chicken pox or



shingles (either face to face or for longer than 15 minutes in the same room) you should report to your doctor immediately as your child may be at risk of developing a more severe form of the infection and may need special treatment with immunoglobulin. If your child gets chicken pox or shingles, you should also report to your doctor immediately for aciclovir to be given. If you are unsure whether your child has had chicken pox prior to starting azathioprine, their immunity should be checked with a simple blood test at that time and the result entered on the parent-held monitoring card.

- If your doctor decides to stop treatment with methotrexate, return any unused medicine to

your pharmacist. Do not flush down the toilet or throw it away.

- If you forget to give your child a dose on the regular day, give it as soon as you remember on the next day or the day after that. Do not give a double dose if it is already time to give the next one.
- Your family doctor (GP) will need to give you a repeat prescription for methotrexate.
- Some medicines will need to be ordered by your local pharmacist- ask your GP for another prescription with enough time (when you have about 2 weeks of your medicine left) to ensure you do not run out.

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.

