

Intravenous methotrexate infusion for non-oncology indications

Information for parents / carers / young people

Introduction

This leaflet contains information about the use of intravenous methotrexate in children and young people in the management of rheumatological conditions.

It tells you:

- how the medicine works
- how it should be given
- whether there are any side effects.

Please also read the general information leaflets available at www.medicinesforchildren.org.uk or available at the hospital pharmacy. This is in addition to any information provided by the manufacturer in the medicine package.

Why have I been given this leaflet?

The leaflet will help you to remember what your doctor has told you about this medicine. It will also help you to decide whether you want to go ahead with this treatment.

For most medicines, information is provided by the manufacturer in the medicine package. This medicine does not have a license for use in children with juvenile idiopathic arthritis (JIA) so the leaflet in the medicine package doesn't tell you everything you need to know. We have written this leaflet to give you some extra information.

What is methotrexate and how does it work?

In JIA and similar conditions the immune system is overactive and attacks normal body tissue, such as the joints. Methotrexate is an immunosuppressant, which means that it dampens down the immune system and slows down/controls the disease. Methotrexate is also important in preventing the generation of HACA antibodies (human anti-chimeric antibodies), associated with prolonged treatment with infliximab. The production of HACA antibodies leads to infliximab insensitivity and/or sensitivity reactions.

If you/your child are unable to tolerate weekly subcutaneous methotrexate or oral methotrexate (due to gastro intestinal symptoms associated with methotrexate, or severe injection anxiety despite psychological intervention), intravenous methotrexate would be an appropriate alternative with each infliximab dose (this may be monthly, every six weeks or every eight weeks depending on how often you/your child receives infliximab).



Remember that your doctor will have thought carefully about which medicine is best for you/your child's condition.

Why does methotrexate not have a license for use in children?

Sometimes a medicine has been licensed for a certain use in adults and later use shows that it works for a similar illness in children. The manufacturer can choose whether they apply to the Government to have the more recent information added to the license. This costs a lot of money and sometimes the manufacturer decides it is not worth their while.

Intravenous methotrexate is made by the manufacturer for the treatment of certain autoimmune conditions and cancers in adults and children. 'Intravenous' means medicine given into a vein through a small plastic tube/cannula.

Methotrexate is made by the manufacturer for the treatment of arthritis in adults. However it is also widely used in children and methotrexate given by injection (injection under the skin) is licensed for children over three years of age for poly articular forms of juvenile idiopathic arthritis (JIA). Intravenous methotrexate is an unlicensed use of a licenced product.

The leaflet called **unlicensed medicines** available at www.medicinesforchildren.org.uk tells you more about medicine licensing regulations. It also tells you why unlicensed medicines are sometimes used.

When should methotrexate not be taken?

There are people with certain medical conditions who should not take methotrexate, or who should take it with extra care.

The manufacturer's leaflet will explain this in more detail. Please tell your doctor if you/your child have/has any of the conditions listed.

Safe, reliable contraception is very important when taking immuno-suppressive medications. Some medications can cause abnormalities to an unborn child during pregnancy and can affect both the male sperm and the female eggs. Please discuss contraception or planning a pregnancy with your doctor or nurse. They can give you information on what risks the medication may cause to you and your baby.

If you think there is a possibility that you are pregnant or your partner may be pregnant please contact your nurse specialist or family doctor immediately.

How is intravenous methotrexate given?

Intravenous methotrexate is given as an infusion over 15 minutes using the same cannula you/your child will be receiving the intravenous infliximab through. The dose is carefully calculated according to your/your child's body surface area. If you/your child are changing from methotrexate tablets or subcutaneous injection then this dose will be converted into the equivalent dose.

Are there any side effects?

Most medicines can cause side effects. The leaflet provided by the manufacturer for methotrexate contains a list of the effects reported for this medicine.

- Intravenous methotrexate may cause feelings of nausea or vomiting, indigestion, headaches and diarrhoea. Anti-sickness medications can be helpful, especially when taken an hour or so before the methotrexate dose.
- Mouth ulcers, hair coming out a little more easily when brushing, and rarely mood disturbance can sometimes occur. Please discuss any concerns with the Paediatric Rheumatology Team.
- It may be recommended that your child/you take folic acid in a tablet or liquid form. Folic acid is a vitamin which

can help to reduce the side effects caused by methotrexate. It is taken in a variety of regimes, but it is never taken on the day of methotrexate.

- Methotrexate can very rarely affect the liver, and blood cell numbers. Your child/you must have a blood test at each infusion. Blood tests allow any such concerns to be spotted early. The effects always wear off when methotrexate is paused or stopped. Sometimes we need to reduce the dose of methotrexate. Please report easy bruising or easy bleeding. If a worry, this may prompt a repeat blood test.
- Methotrexate can suppress the immune system therefore there is an increased risk of infection. All possible infections should be reviewed by a doctor.
- There is an increased risk of developing a severe case of chicken pox or measles. If your child/you is/are in contact with chicken pox or measles while on methotrexate, contact your doctor.

Vaccines

Due to the immunosuppressive nature of the medicine, please have an influenza (flu) vaccine every winter at your GP Practice. We recommend a dose of PPV-23 for all patients aged two years old and over and on immunosuppression (providing at least 8 weeks after PCV-13 vaccination)

Future vaccines including travel vaccines should be discussed with the Team as live vaccines should be avoided.

As with all immunosuppressant medication we recommend safe sun exposure, and in particular avoiding sun burn, due to an increased risk of long term skin damage.

Everyone reacts differently to medicines. It is very unlikely that you/your child will have all the listed effects.

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Will intravenous methotrexate affect any other medicines?

Methotrexate may affect or be affected by some other medicines. The most common interaction is with trimethoprim (an antibiotic), which can increase methotrexate blood levels and cause problems. There are other drugs that cause a similar effect. You should tell your/your child's doctor or pharmacist about all the other medicines. This includes any medicines prescribed by another doctor as well as medicines bought from a pharmacy or supermarket and any herbal remedies.

If your you/your child are prescribed a new medicine (including vaccinations), or you want to buy a medicine (for you/your child) from a pharmacy, it is important that you tell the doctor or pharmacist about all the medicines you/your child take, including methotrexate. You should also tell your/your child's dentist.

Non-steroidal anti-inflammatory drugs (NSAIDs) can be given with methotrexate under the supervision of the Paediatric Rheumatologist. Do not take/give your child NSAIDs that have not been recommended by the Paediatric Rheumatology Team. Everyone reacts differently to medicines. You/your child may have some side effects or none at all.

How can I find out more?

This leaflet has been written to provide general information about the use of intravenous methotrexate in children/young people with a non-oncology condition. If you have any more specific questions or concerns, please speak to one of the following:

Children's Rheumatology Nursing Team
0113 392 0683

Paediatric Rheumatology secretary
0113 392 0666