PATIENT INFORMATION LEAFLET

METHOTREXATE FOR SKIN CONDITIONS

Written for parents, children and young people

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about methotrexate. It explains what it is, how it works, how it is used to treat skin conditions, and where more information can be found about it.

WHAT IS THE IMMUNE SYSTEM AND HOW DOES IT AFFECT THE SKIN?

The immune system protects the body from illness. It helps fight off infections, germs and viruses.

In some skin conditions, the immune system becomes overactive and starts to attack healthy skin. This causes inflammation, which can make the skin itchy, sore, dry, flaky or red (or darker than your usual skin tone).

Conditions like eczema and psoriasis are examples for this. They are usually long-term (chronic) and can flare up from time to time.

WHAT CAN BE DONE ABOUT INFLAMMATORY SKIN CONDITIONS?

There are many treatments that help calm inflammation and relieve symptoms, like itching and irritation. These include topical treatments (creams and ointments that go directly on the skin).

They include:

- emollients
- topical corticosteroids (steroid creams and ointments)
- topical calcineurin inhibitors

If topical treatments are not enough, or if the condition is severe, your healthcare professional might suggest other medicines that work on the immune system. Methotrexate is one of these medicines.

WHAT IS METHOTREXATE AND HOW DOES IT WORK?

Methotrexate is a medicine that tells the immune system to slow down. It is known as an **immunomodulator** – this means it changes how the immune system works.

At low doses, it can be used to treat skin conditions by calming the immune system. This reduces inflammation and helps the skin feel less itchy and sore and can improve your symptoms.

Methotrexate can also be used at higher doses as an **immunosuppressant** to treat other conditions such as cancer. An immunosuppressant lowers (or supresses) the immune system's activity to help stop the growth of cancer cells.

WHICH SKIN CONDITIONS ARE TREATED WITH METHOTREXATE?

Methotrexate is used to treat skin conditions such as:

- eczema
- psoriasis

It is also used in other inflammatory skin conditions, including:

- psoriatic arthritis
- sarcoidosis
- scleroderma
- dermatomyositis

Methotrexate is also commonly used in children and young people to treat other inflammatory conditions such as arthritis.

IS METHOTREXATE SAFE?

It is important that we always consider the safety of a medication before we take it. This involves balancing the possible risks and possible benefits. Methotrexate has been

used for many years to manage different health conditions. There is now strong evidence that low-dose methotrexate can safely help manage skin disease in children and young people, with a low risk of possible problems.

Methotrexate is used off-licence in children under 16 with inflammatory conditions. This means it is not officially licensed for this use, but it has been tested and is considered safe and effective. For more information, see the resources for unlicensed and off-licence medicines in the last section of this leaflet.

WHEN AND HOW SHOULD METHOTREXATE BE TAKEN?

Methotrexate can be taken as a tablet, liquid, or injection. It should be taken **once a week,** and this should be on the same day each week. Your dermatologist will agree a suitable day with you and document this in your records and letters.

> Methotrexate should never be taken daily. It is very important to take it exactly as prescribed.

You can take methotrexate as a:

Tablet or liquid (taken by mouth):
Methotrexate tablets should be taken with food and swallowed whole – do not crush or chew them. Always wash your hands before and after handling methotrexate tablets.

Injection:
Given under the skin (subcutaneous), or into a muscle (intramuscular) (such as the thigh or buttocks. You will receive training on how to inject the medicine, so you can do this at home.

WHAT DOSE OF METHOTREXATE SHOULD BE TAKEN?

The dose of methotrexate depends on body weight. A usual dose for children and young people is around 0.4mg per kg **per week.**

Dermatologists usually prescribe methotrexate in 2.5 mg tablets. These tablets **must not be confused** with 10 mg tablets, which are a much higher strength and look similar.

If you miss your dose, you can take it within 48 hours. But if more than two days have passed, methotrexate should not be taken that week. The next dose should be taken on the usual day the following week.

Care should be taken to make sure that the correct dose and strength has been prescribed and dispensed to you.

> Always check the dose and strength with your pharmacist or doctor before taking methotrexate. If you take too much methotrexate, contact your doctor immediately, as treatment may be needed.

Your healthcare professional will adjust your dose of methotrexate according to how your body reacts to the medicine. If needed, they might switch you from tablets to injections to make the treatment more effective and reduce side effects.

HOW LONG DOES IT TAKE TO WORK?

Methotrexate can take 1 to 3 months to show improvement. Your healthcare professional may change the dose during this time to help improve your skin condition.

HOW LONG DO I NEED TO TAKE METHOTREXATE?

The aim of treatment is to keep your skin condition under control using the lowest possible dose that works well. How long you stay on methotrexate depends on why it was prescribed. Some people may need to take it for several years.

WHAT ARE THE POSSIBLE SIDE EFFECTS?

As with any medication, there are some possible side effects from taking methotrexate.

However, many children and young people have no side effects at all. If they do occur, they can often be managed.

Some people feel sick after taking methotrexate. This can sometimes be improved by:

- taking methotrexate at bedtime
- having it with a drink that contains caffeine, such as cocoa
- using anti-sickness medicines, such as ondansetron

Methotrexate given by injection rather than tablets (oral medicine) can also be considered to reduce side effects. You can talk to your doctor about this.

It is important to see a doctor and consider temporarily stopping methotrexate if any of the following symptoms occur:

- a sore throat, fever or any other symptoms or signs of infection
- mouth ulcers (may require an urgent blood test if these are severe)
- unexplained bruising or bleeding from the gums
- nausea, vomiting, abdominal pain or dark urine
- new breathlessness or a cough.

If you develop an infection and need antibiotics, stop methotrexate until you have finished the full course and feel better.

If you notice any new symptoms that may be a side effect of methotrexate, seek medical advice.

WHAT SHOULD I DO IF THERE ARE SIDE EFFECTS?

The most common side effects can be managed. For example:

- Take methotrexate at night to sleep through discomfort.
- Take methotrexate on Friday nights to avoid missing school or other activities during the week.
- Consider switching to injections if the tablets cause nausea and sickness.
- Taking high doses of folic acid (up to 6 days a week, except methotrexate day) can be considered, if required.
- Anti-sickness medicines can be prescribed, and some children and young people find these helpful.

Talk to your doctor about which option might help you.

HOW IS METHOTREXATE MONITORED FOR SIDE EFFECTS?

People on methotrexate will have regular check-ups to ensure the medicine is working and to monitor for side effects. Blood tests are usually done:

- Before starting treatment
- around 1 month after starting treatment
- every 3-4 months (may vary depending on the test results and response to treatment).

Your doctor or nurse specialist will advise you how often these tests will be needed.

The reasons for the blood tests are:

- To make sure that it is safe to start or continue methotrexate
- To monitor for possible side effects or changes in your body
- To adjust the dose if needed.

National registries: The BAD Biologic Interventions Register (BADBIR) (psoriasis) and ASTAR (eczema) register

You may be asked to take part in a national register if you are prescribed methotrexate. These registers collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use medicines. No information will be passed to the register without your informed consent.

CAN VACCINES BE GIVEN WHILE TAKING METHOTREXATE?

- The current guidelines state that people taking methotrexate (up to 25 mg per week) can receive 'live' vaccines. Live vaccines contain small amount of weakened pathogen (virus or bacteria) which may cause infection if your immune system is lowered. These include MMR (measles, mumps, rubella), polio and varicella (chickenpox). These vaccines may be less effective, and your doctor will check if they are suitable for you.
- For yellow fever vaccine, specialist advice may be needed, as there is limited safety data.
- If you have never had chickenpox, it may be best to get vaccinated before starting methotrexate. If this is not possible and you come into contact with someone with chickenpox or shingles, contact your doctor straight away. You may need special preventative treatment.
- Vaccines for flu, pneumococcal infection or COVID are safe and recommended while taking methotrexate. If you have not been offered these, please ask your doctor.

CAN OTHER MEDICINES BE TAKEN AT THE SAME TIME AS METHOTREXATE?

Some medicines interact with methotrexate, and this could be harmful. Always tell your healthcare team that you are taking methotrexate.

Most medicines however can be taken alongside low dose methotrexate. Painkillers such as paracetamol and ibuprofen are usually safe. Talk to your healthcare team if you have any concerns or questions about new medicines.

Folic acid and methotrexate

Folic acid is a vitamin often taken with methotrexate. It helps reduce side effects such as nausea and tiredness. It should be taken between one and six times per week, as directed. **But it should not be taken on the same day as methotrexate.**

Taking folic acid 6 days a week has been shown to help prevent problems such as nausea.

ARE THERE ANY OTHER THINGS TO KNOW?

Methotrexate can cause harm to an unborn child. It is important to avoid pregnancy while on methotrexate. If you are sexually active, use effective and reliable contraception before and during methotrexate treatment. Talk to your doctor if you are planning for pregnancy or if you or your partner become pregnant. In the case of pregnancy (yours or your partner's), inform your doctor immediately.

Avoid alcohol use and smoking while taking methotrexate. Talk to your doctor about this if you have any concerns.

Methotrexate does not affect fertility. People who took high doses of methotrexate for cancer as children have gone on to have healthy children as adults.

WHERE CAN I GET MORE INFORMATION ABOUT METHOTREXATE?

Speak to the doctor, nurse or pharmacist for more information. This leaflet does not include every possible all the side effect . For further details, please look at the drug information sheet in your methotrexate prescription pack.

Weblinks to other relevant sources:

Information on unlicensed and off-licence medicines:
www.medicinesforchildren.org.uk/advice-guides/general-information-about-medicines/unlicensed-medicines/

Jargon Buster:
www.skinhealthinfo.org.uk/support-resources/jargon-buster/

It is important to report suspected side effects of medicines. The Medicines and Healthcare products Regulatory Agency (MHRA) manages the Yellow Card scheme. This scheme collects information and safety concerns about medicines and medical devices. Anyone can report these side effects or concerns by using:

- the Yellow Card website www.mhra.gov.uk/yellowcard or
- the Yellow Card app

Please note that the British Association of Dermatologists provides web links to additional resources to help people access a range of information about their treatment or skin condition. The views expressed in these external resources may not be shared by the BAD or its members. The BAD has no control of and does not endorse the content of external links.

BSPAD
BRITISH SOCIETY FOR PAEDIATRIC AND ADOLESCENT DERMATOLOGY

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Society for Paediatric and Adolescent Dermatology (BSPAD) and the British Association of Dermatologists (BAD): individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

BRITISH ASSOCIATION OF DERMATOLOGISTS

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