PATIENT INFORMATION LEAFLET

UPADACITINIB

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about upadacitinib. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

WHAT IS UPADACITINIB AND HOW DOES IT WORK?

Upadacitinib is a type of drug known as a Janus kinase (JAK) inhibitor. It helps with conditions like atopic eczema (or atopic dermatitis) by blocking some of the pathways that cause inflammation in the skin.

WHAT SKIN CONDITIONS ARE TREATED WITH UPADACITINIB?

Currently, upadacitinib is licensed to treat moderate to severe atopic eczema (also known as atopic dermatitis) and other, non-dermatological conditions such as psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease.

WHY HAVE I BEEN SELECTED FOR TREATMENT WITH UPADACITINIB?

Upadacitinib is used for moderate to severe atopic eczema in adults and children aged 12 years and older. This medication is for those who have tried standard immunosuppressive treatments but:

- have not benefitted from them
- were unable to tolerate them
- or other treatments were unsuitable.

HOW DO I TAKE UPADACITINIB?

Upadacitinib is taken by the mouth once a day. It can be taken at any time of the day, with or without food. You should swallow the tablet whole with water. Do not split, crush, chew or break the tablet.

WHAT DOSE SHOULD I TAKE?

The recommended dose of upadacitinib is 15mg or 30mg once daily.

The recommended dose for adults is 15 mg or 30 mg. This daily dose may be increased or decreased depending on how well upadacitinib works for the adult taking it.

For children aged 12 years and older, and people of 65 years and above, the recommended dose is 15 mg once daily.

HOW LONG WILL I NEED TO TAKE UPADACITINIB BEFORE IT HAS AN EFFECT?

Upadacitinib is an ongoing treatment to control eczema rather than a treatment that is used for a fixed amount of time.

Many people who benefit from this treatment will notice an improvement within the first few weeks of starting this medication. Others may see more gradual and further improvements over the first 3 months of treatment. If upadacitinib does not address the symptoms of eczema effectively within 16 weeks of initiating treatment, the medication may be stopped.

WILL UPADACITINIB CURE MY SKIN CONDITION?

Atopic eczema cannot be cured. Instead, treatment aims to control it. Upadacitinib can help to improve the condition of your skin, reduce itching, flares, sleep disturbance, and the impact of eczema on your quality of life.

WHAT ARE THE COMMON SIDE EFFECTS OF UPADACITINIB?

Like all medicines, upadacitinib can cause side effects, although not everybody gets them.

Serious side effects
Talk to your doctor or get medical help straight away if you get any signs of:

- Shingles is a painful blistering rash, typically on one side of the body. Shingles is caused by the varicella zoster (or chicken pox) virus – common (may affect up to 1 in 10 people).
- Infection of the lung (pneumonia), which may cause shortness of breath, fever, and a cough with mucus – common (may affect up to 1 in 10 people).
- Infection in the blood (sepsis) – uncommon (may affect up to 1 in 100 people).
- Allergic reaction, which may cause a rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat – uncommon (may affect up to 1 in 100 people).

Very common (may affect more than 1 in 10 people)

- Throat and nose infections.
- Acne: a condition characterised by comedones (blackheads and whiteheads) and pus-filled spots (pustules). Among those taking upadacitinib, acne often affects the face and can generally be managed with topical therapies or oral medications.

Common (may affect up to 1 in 10 people)

- Non-melanoma skin cancer: You should protect yourself from too much exposure to sunlight by not sunbathing, wearing suitable clothing (e.g. long sleeves and hat that protects your face and ears), and using sunscreens with a sun protection factor (SPF) of at least 30 and a star rating of at least 4. If you detect any new swellings or lumps, or changes in your skin, which last more than two weeks, you should inform your doctor as soon as possible.
- Cold sores (herpes simplex). Herpes simplex is a common viral infection that presents with blisters, most frequently located on the mouth (known as cold sores), and in the genital area.
- Altered blood tests: Increase in an enzyme called creatine kinase, shown by blood tests, high levels of cholesterol, anaemia (low red blood cells), leukopenia (low white blood cells), Increased levels of liver enzymes (sign of liver problems).
- Feeling sick in the stomach (nausea).
- Headache
- Fatigue (feeling unusually tired and weak)
- Weight gain
- Urinary tract infection
- Inflammation (swelling) of the hair follicles
- Flu (influenza)

Uncommon (may affect up to 1 in 100 people)

- Thrush: a yeast (fungal) infection that results in white patches in the mouth and throat
- Altered blood tests: high levels of triglycerides (a type of fat) in the blood.
- Diverticulitis: painful inflammation of small pockets in the lining of your intestine
- Tears in the stomach or intestines (gastrointestinal perforation). This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids. Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.

WHAT ARE THE RARE SIDE EFFECTS OF UPADACITINIB?

We know that JAK inhibitors can cause serious side effects. Clinical trials for rheumatoid arthritis looked at the effects of a JAK inhibitor called Tofacitinib, compared with other drugs known as tumour necrosis factor (TNF)-alpha inhibitors. Results showed that patients taking JAK inhibitors were at a higher risk of serious infections and complications. These included major cardiovascular problems (such as heart attack or stroke), cancer, blood clots in the

lungs and in the deep veins of the body, and death in patients with certain risk factors. Following this, the Medicines and Healthcare products Regulatory Agency issued a warning for all JAK-inhibitors, including those used for the treatment of atopic eczema, not just the one used in the clinical trials for rheumatoid arthritis (tofacitinib).

The risk of experiencing these serious side effects is greater if you are of 65 years or older, have an already increased risk of major cardiovascular problems or cancer, or if you smoke or have smoked in the past for a long time. People with these risk factors may not be offered upadacitinib unless there is no alternative or a balanced assessment of risks versus benefits has been carefully considered with your dermatologist.

Major cardiovascular problems, such as heart attack and stroke. If, at any stage during your treatment, you experience chest pain or tightness (which may spread to arms, jaw, neck and back), weakness in arms and legs or slurred speech, stop taking upadacitinib and get emergency medical help.

- Blood clots. Blood clots in the veins of the legs or lungs and arteries can happen with upadacitinib. If, at any stage in your treatment, you experience chest pain, shortness of breath, or a swollen and painful leg, stop taking upadacitinib and get emergency medical help.

HOW WILL I BE MONITORED FOR THE SIDE EFFECTS OF UPADACITINIB?

Before you start taking upadacitinib, you will have a consultation with your dermatologist. You will be asked about any current or past infections (such as human immunodeficiency virus (HIV) infection, viral hepatitis, tuberculosis, frequent cold sores, and shingles), and whether you have a history of cancer, blood clots, heart disease or strokes. Blood tests will be performed before starting the medication. It is important to tell your dermatologists if you are or planning to become pregnant or if you are breastfeeding. It is recommended that all patients have up to date immunisations before starting Upadacitinib (these cover most of the common infections, including pneumonia, influenza, shingles and COVID-19).

During treatment with upadacitinib, you will have blood test monitoring regularly to check your full blood count, liver function and lipid profile (which includes your cholesterol and triglyceride levels) while you are taking upadacitinib.

CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON UPADACITINIB?

Patients on upadacitinib should not be given live vaccines, such as measles, mumps and rubella (MMR), tuberculosis (BCG), yellow fever and shingles live vaccine. Inactivated or non-live vaccinations such as Covid, a pneumococcal and flu vaccinations (except the nasal flu vaccine) are safe. People aged 50 and above, will be offered two doses of an inactivated (non-live) Shingles vaccine called Shingrix (given 8 weeks to 6 months apart).

You should always check with your healthcare professional when having a vaccination and make them aware that you are on upadacitinib.

DOES UPADACITINIB AFFECT FERTILITY OR PREGNANCY?

You should not take upadacitinib if you are pregnant or breastfeeding. Women of who can get pregnant must use effective contraception during treatment and for at least 4 weeks after treatment. Do not breastfeed during treatment with upadacitinib and for 6 days after your last dose.

It is currently unknown whether upadacitinib affects fertility. If you become pregnant whilst taking upadacitinib, talk to your doctor immediately.

MAY I DRINK ALCOHOL WHILE TAKING UPADACITINIB?

Alcohol may be consumed during treatment with upadacitinib. If you have an underlying liver problem, you must let your healthcare professional know. To keep health risks from alcohol to a low level, it is safest not to drink

more than 14 units of alcohol per week regularly.

(https://www.nhs.uk/better-health/drink-less/).

CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS UPADACITINIB?

Before you start treatment with upadacitinib, please let your dermatologist know of the medicines you are taking, including prescribed and over-the-counter supplements or herbal treatments. After starting upadacitinib, you should let any doctor treating you know that you are taking this medication.

Taking other medicines that suppress the immune system together with upadacitinib has not been studied, and it is currently not recommended. Certain antibiotics, antifungals, antiretrovirals (medications for HIV) and anti-epileptic medications can alter the amount of upadacitinib in your body.

Avoid food or drink containing grapefruit during treatment with upadacitinib, as these may increase the risk of side effects by increasing the amount of upadacitinib in your body.

WHERE CAN I GET MORE INFORMATION ABOUT UPADACITINIB?

You should speak to your prescribing doctor or pharmacist if you want to know more about treatment with upadacitinib.

Always read the drug information sheet that is provided as an insert in the packaging of the medication. It can also be obtained online at https://www.medicines.org.uk/emc/search?q=%22upadacitinib%22

Jargon Buster
https://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 (BAD) 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.

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: 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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