

Patient information factsheet

Upadacitinib for the treatment of Crohn's disease and ulcerative colitis

We have given you this factsheet because you have been diagnosed with an inflammatory bowel disease (IBD) called Crohn's disease or ulcerative colitis and have been prescribed a medication called upadacitinib as part of your treatment programme. This factsheet explains how you should take upadacitinib and the possible side effects. We hope it will help to answer some of the questions you may have. If you have any further questions or concerns, please contact us using the details at the end of this factsheet.

What is upadacitinib?

Upadacitinib is a type of medication known as a Janus kinase (JAK) inhibitor. JAKs are proteins that play a part in activating your immune response, helping you to fight infections. However, JAKs can also cause unwanted inflammation in the body.

JAK inhibitors work by limiting the action of JAKs, reducing gut inflammation in people with IBDs like Crohn's disease and ulcerative colitis.

Is upadacitinib suitable for everyone?

You should **not** have upadacitinib if you:

- are pregnant
- think you may be pregnant
- are trying to conceive or become pregnant
- are breastfeeding
- have active tuberculosis (an infection that usually affects the lungs)
- have active serious infections (including localised infections)
- have severe hepatic impairment (liver failure)

Upadacitinib should be used with caution if you:

- are aged 65 years or older
- have a history of atherosclerotic cardiovascular disease (heart attack or stroke) or other cardiovascular risk factors (for example, former long-time smoker)
- have any risk factors for blood clots, such as:
 - previous deep vein thrombosis (a blood clot in a vein)
 - previous pulmonary embolism (when a blood clot blocks a blood vessel in your lungs)
 - use of combined hormonal contraceptives or hormone replacement therapy
 - immobilisation (prolonged periods of sitting or bed rest)
 - a history of blood clotting (coagulation) disorders
- currently have cancer or have had cancer in the past
- have diverticular disease (a condition that affects the large intestine)

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How is upadacitinib given?

Upadacitinib comes as slow-release tablets. You must swallow the tablets whole with water. You must not chew, cut or crush them.

You should take one tablet once a day at the same time of day. It can be taken with or without food. Avoid grapefruit and grapefruit juice while taking this medication as it can affect the way the medication works.

It can take two to eight weeks before you notice an improvement in your symptoms.

What dose should I take?

Crohn's disease	Ulcerative colitis
<ul style="list-style-type: none">Initial dose of 45mg daily for 12 weeks.Maintenance dose of 30mg or 15mg daily (or stop if no response to the medication).	<ul style="list-style-type: none">Initial dose of 45mg daily for 8 weeks (may continue for a further 8 weeks for some people).Maintenance dose of 30mg or 15mg daily (or stop if no response to the medication).

We will review you regularly to determine your maintenance dose. We will aim to use the lowest effective dose to control your symptoms.

Some medications affect the way upadacitinib works. If you are on any of these medications, we may reduce your dose.

How long will I need to take upadacitinib for?

If upadacitinib helps to treat your IBD, you will remain on the medication long term.

Do not stop taking upadacitinib without discussing this with us first.

What should I do if I miss a dose?

If you miss a dose, take it as soon as you remember that day. If you miss a whole day, skip the missed dose and take the next dose at your normal time. **Do not double up the dose.**

How will I receive this medication?

Upadacitinib cannot be supplied by your general practitioner (GP). Your first prescription of this medication will be arranged through our hospital's outpatient pharmacy. You can either collect this first prescription on the day it is created, or it will be delivered to your home usually within three working days. Your following prescriptions will then be delivered directly to your home by a homecare provider called Alcura.

Alcura

Telephone: **0800 980 0686** (Monday to Friday, 8am to 6.30pm and Saturday, 9am to 1pm)

Contact us using the details at the end of this factsheet or via the messaging service on My Medical Record two to three weeks before you are due to finish your first prescription of 45mg upadacitinib tablets for a review of your treatment. For more information about My Medical record, visit: www.uhs.nhs.uk/for-patients/my-medical-record

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What are the possible side effects?

As with all medications, upadacitinib can cause some side effects. The most common side effects of upadacitinib are:

Increased risk of infection

As upadacitinib affects the immune system, it can make you more likely to develop infections, such as a cold, cough or sore throat, as your body isn't able to fight these off as well as it usually would. Upper respiratory tract infections affect around 1 in 10 people taking upadacitinib. Serious infections (sepsis) are far less common, affecting 1 in 100 to 1 in 1,000 people taking upadacitinib. If you have repeated infections, such as a chronic cough or regular fevers, you should contact us using the details at the end of this factsheet.

Stop taking upadacitinib if you have:

- a fever (a high temperature of 38°C or above)
- flu-like or COVID-19 symptoms
- been prescribed antibiotics for an infection

You can then resume taking upadacitinib **one week after** you feel better, or you have finished the course of antibiotics.

Taking upadacitinib can increase your risk of shingles (an infection that often causes a painful rash). Contact your GP for a review if you develop any symptoms of shingles, such as pain, burning or tingling of the skin or a new skin rash. If you are treated for shingles, you should stop taking upadacitinib until all the shingles blisters have dried and scabbed over.

Acne

Acne is a common skin condition that causes spots, oily skin and sometimes skin that's hot or painful to touch. Acne affects 1 in 10 to 1 in 100 people taking upadacitinib and tends to improve once the dose is reduced.

If you are unable to treat your acne using over-the-counter treatments, contact your GP for advice or ask them for a referral to dermatology.

Blood clots

Blood clots are rare, especially if you do not have any factors that increase your risk, such as smoking.

However, having active Crohn's disease or ulcerative colitis can increase your risk of getting blood clots. Effective treatment that gets your IBD under control may help reduce the risk, so it's a balance between the risks and benefits.

Contact your GP or NHS 111 immediately if you experience any **new** symptoms of a blood clot:

- a painful, red, swollen leg
- sharp chest pain
- breathlessness

Increased risk of cancer

As upadacitinib weakens the immune system, it may increase your risk of getting certain cancers in the future. However, there is currently not enough evidence to know the exact risk.

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Upadacitinib may make your skin more sensitive to sunlight, which can increase your risk of non-melanoma skin cancer. Avoid being exposed to strong sunlight and do not use a sun lamp or sun bed.

You can help protect your skin by:

- using a high sun protection factor (SPF) sunscreen
- wearing a hat and clothes that cover your arms and legs
- staying in the shade (where possible)

Regularly check your skin and contact your GP if you have any:

- skin growths
- new moles
- moles that have changed

You should also attend any routine cancer screening appointments you are invited to.

For the full list of possible side effects that may occur with upadacitinib, please read the leaflet supplied with your medication.

Will I need to be monitored?

You will need to have regular blood tests every three months while you take this medication. Please contact us if you run out of blood test forms.

You will also need to have a cholesterol blood test when you first start taking the medication and then again after three months. This can be arranged at the same time as your regular blood tests.

You can arrange to have these blood tests in hospital or at your local GP surgery.

Can I have vaccinations?

You should not have any **live vaccines** when you are taking upadacitinib, such as:

- polio vaccine
- typhoid fever vaccine
- yellow fever vaccine
- MMR (measles, mumps and rubella) vaccine

The following **non-live vaccines** are safe to have:

- COVID-19 vaccine
- yearly flu vaccine
- pneumococcal vaccines
- shingles (Shingrix brand) vaccine (if applicable)

Can I take other medications at the same time as upadacitinib?

Check with your GP before you take any new medication while you are taking upadacitinib, as some medications (including clarithromycin, ketoconazole, rifampicin and phenytoin) can affect the way that upadacitinib works.

Check with your pharmacist before you take any over-the-counter medication, including herbal remedies.

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Can I take upadacitinib if I am pregnant or breastfeeding?

You must **not** take upadacitinib if you are pregnant or breastfeeding.

Contraception

To prevent pregnancy, you should use two methods of contraception (condoms and one other method) while taking upadacitinib and for at least four weeks after your last dose.

Can I smoke while taking upadacitinib?

Smoking increases your risk of blood clots and is known to worsen control of Crohn's disease. It can affect healing after surgery and contains toxins which cause cancer. If you are a current smoker, we strongly encourage you to stop smoking. If you need guidance or support with stopping smoking, contact your GP or your local stop smoking support service. To find your local service, visit: www.nhs.uk/service-search/other-health-services/stop-smoking-support-services

Safety information

We recommend that you always keep a copy of your regular medication list with you. This may be in a purse or wallet, or in the emergency section of your smartphone.

If you are given a patient safety card by Alcura for upadacitinib, always keep this on you.

Contact us

If you have any questions or concerns, please contact us.

Inflammatory bowel disease (IBD) service

Telephone: **023 8120 5363** (Monday to Friday, 9am to 6pm)

If we are unable to answer your call, please leave a message with your **name, date of birth, hospital number and a brief reason for your call**. We will get back to you as soon as we can.

Alternatively, you can send us a message via My Medical Record.

Useful links

www.crohnsandcolitis.org.uk

www.crohnsandcolitis.org.uk/info-support/information-about-crohns-and-colitis/all-information-about-crohns-and-colitis/treatments/upadacitinib

www.nhs.uk/conditions/crohns-disease

www.nhs.uk/conditions/ulcerative-colitis

www.crohnsandcolitis.org.uk/info-support/information-about-crohns-and-colitis/all-information-about-crohns-and-colitis/living-with-crohns-or-colitis/smoking-or-vaping-with-crohns-or-colitis

www.medicines.org.uk/emc/product/13935/pil

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If you are a patient at one of our hospitals and need this document translated, or in another format such as easy read, large print, Braille or audio, please telephone **0800 484 0135** or email **patientsupporthub@uhs.nhs.uk**

For help preparing for your visit, arranging an interpreter or accessing the hospital, please visit **www.uhs.nhs.uk/additionalsupport**

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