#### PATIENT INFORMATION LEAFLET

#### RITLECITINIB



#### WHAT ARE THE AIMS OF THIS LEAFLET?

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

## WHAT IS RITLECITINIB AND HOW DOES IT WORK?

Ritlecitinib is an oral medication (capsule) known as a kinase inhibitor which inhibits (blocks) Janus Kinase (JAK) 3 and tyrosine kinase (TEC). It works by reducing the activity of enzymes (messenger proteins) in the body called "kinases" which cause inflammation. By doing so, it suppresses the immune system, which helps reduce inflammation and promotes hair regrowth in conditions like severe alopecia areata. Alopecia areata is an autoimmune condition, meaning the immune system is in overdrive and attacks the roots of the hair causing hair loss. The hair loss can affect the scalp, eyelashes/eyebrows, facial and body hair. Ritlecitinib aims to treat all areas of hair loss.

### WHAT CONDITIONS ARE TREATED WITH RITLECITINIB?

Ritlecitinib is currently licensed to treat severe alopecia areata in adults and young people aged 12 years and older.

### WHY HAVE I BEEN SELECTED FOR TREATMENT WITH RITLECITINIB?

The health professional caring for you will have assessed the extent of your hair loss and how it is affecting you. Ritlecitinib will then be offered to treat severe alopecia areata.

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

Many people who benefit from ritlecitinib notice an improvement in hair growth within

the first 24 weeks (6 months) of starting this medication.

The effect of treatment will be assessed by your healthcare professional from 36 weeks (9 months). If there is little improvement, the treatment may be stopped.

#### **HOW DO I TAKE RITLECITINIB?**

Ritlecitinib is a capsule taken by mouth at any time once a day, with or without food.

#### WHAT DOSE SHOULD I TAKE?

The recommended dose of ritlecitinib is 50 mg once daily.

If you have reduced kidney or liver function, your dose remains the same. If you have severe kidney or liver problems, then ritlecitinib would not be recommended.

#### WHAT ARE THE COMMON SIDE EFFECTS OF RITLECITINIB?

Most patients tolerate ritlecitinib well and do not experience any unwanted effects. However, there are some common side effects. These include:

- Acne is a widespread condition characterised by comedones (blackheads and whiteheads) and pusfilled spots (pustules). Among people taking ritlecitinib, acne often affects the face and can generally be managed with topical therapies (creams, ointments, gels, etc.) applied directly to the skin.
- Shingles is a painful blistering rash, typically in a small area on one side of the body. Shingles is a recurrence of chickenpox (the varicella zoster virus). Antiviral pills are prescribed to treat shingles.
- Other common side effects include hives (urticaria), diarrhoea, headache, dizziness, rash, inflammation



(swelling) of the hair follicles which may be itchy or painful (folliculitis), infections (upper respiratory tract infections).

There can also be an increase in an enzyme called creatine phosphokinase. This can be checked by a blood test.

Currently, we do not have enough information to know if treatment with ritlecitinib is associated with serious side effects such as an increased risk of cancer. You should protect yourself from too much exposure to sunlight by not sunbathing, wearing suitable clothing (e.g. long sleeves and a 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 health professional as soon as possible.

#### WHAT ARE THE RARE SIDE EFFECTS OF RITLECITINIB?

Rarely, ritlecitinib affects platelets in the blood (these prevent bleeding by helping blood to clot) which can be shown by a blood test.

It can also lower lymphocyte count (these are a type of white cell in the blood) which can be shown by a blood test.

Rarely, ritlecitinib may cause an increase in liver enzymes in the blood, which may suggest liver damage or stress

Rarer side effects include cardiovascular problems such as heart attack, stroke, or serious life-threatening blood clots in the lungs or legs.

It is not fully known what the effect of ritlecitinib has on the nervous system. Some animal studies have reported side effects relating to the nervous system. Further research has suggested that these findings are not clinically relevant to people. if you develop unexpected neurological symptoms such as hearing loss, muscle weakness or stiffness, problems with your vision, seizures or memory loss to discuss with their clinician.

If you do feel unwell whilst taking this medication it is important to contact your health professional immediately.

#### HOW WILL I BE MONITORED FOR THE SIDE EFFECTS OF RITLECITINIB TREATMENT?

Before starting ritlecitinib, you will have a consultation with your health professional. 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 blood tests will be performed.

Before starting treatment and 4 weeks after starting treatment, you will have regular blood tests to monitor your full blood count, liver function and lipid profile (this includes your cholesterol and triglyceride levels).

It is important to tell your health professional if you are or planning to become pregnant and if you are breastfeeding.

# CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON RITLECITINIB?

People taking ritlecitinib should not receive live vaccines, such as those for polio (poliomyelitis), rubella (German measles), and yellow fever. Inactivated or non-live vaccinations, such as COVID-19, pneumococcal, and flu vaccines (except the nasal flu vaccine), are safe.

You should always check with your healthcare professional when having a vaccination and make them aware that you are taking ritlecitinib. (For further information on immunisations for people on immune-suppressing medicines, please see the patient information leaflet here).

#### DOES RITLECITINIB AFFECT FERTILITY OR PREGNANCY/ BREASTFEEDING?

You should not take ritlecitinib if you are pregnant, trying to get pregnant or breastfeeding. People of childbearing age must use effective contraception during treatment and for one month following the final dose of treatment. There is little information on its effect on fertility for women of childbearing age or men.

#### CAN I DRINK ALCOHOL WHILE TAKING RITLECITINIB?

Alcohol may be consumed during treatment with ritlecitinib. To keep health risks from alcohol low, it is safest not to drink more than 14 units of alcohol per week regularly. (https://www.nhs.uk/Live-well/alcohol-advice/calculating-alcohol-units/).

### CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS RITLECITINIB?

Before starting treatment with ritlecitinib, inform your health professional about all medicines you are taking, including prescribed and over-the-counter supplements or herbal treatments. After starting ritlecitinib, it is important to tell any health professional treating that you are taking this medication.

When taking ritlecitinib, it is currently not recommended to take other medicines that suppress the immune system, as these have not been studied.

If you have you have an intolerance to lactose, contact your health professional before taking this medicine as ritlecitinib contains lactose.

#### WHERE CAN I GET MORE INFORMATION ABOUT RITLECITINIB?

You should speak to your prescribing health professional or pharmacist if you want to know more about treatment with ritlecitinib.

There is also a drug information sheet provided as an insert in the packaging of the medication. It can also be obtained online at www.medicines.org.uk/emc/product/15257

Weblinks to other relevant sources:

Jargon Buster:

www.skinhealthinfo.org.uk/supportresources/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 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

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