



RISANKIZUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about risankizumab (Skyrizi®). 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 risankizumab and how does it work?

Risankizumab is a biologic medicine that has been designed to treat psoriasis. It works by specifically targeting a chemical messenger (known as a 'cytokine') in the body called 'interleukin-23' (IL-23). We know that IL-23 is one of the main causes of inflammation in psoriasis, and by blocking it risankizumab can improve symptoms of psoriasis.

What skin conditions are treated with risankizumab?

Risankizumab is used to treat psoriasis.

Why have I been selected for treatment with risankizumab?

You have psoriasis which is severe enough to require treatment based on national guidelines. These include failure to improve on other treatments such as methotrexate. Alternatively, there may be safety reasons why you cannot receive these standard treatments, or they may have been tried but caused you problems so you had to stop them.

How long will I need to take risankizumab before it has an effect?

Some improvement in your psoriasis may occur in the first few weeks of treatment but it can take 4 months to see the full benefit. In clinical trials, more than 8 out of 10 patients were clear or nearly clear of their psoriasis by 4 months. If no significant improvement occurs the treatment will be stopped.

How do I take risankizumab?

Risankizumab is given as an injection under your skin (subcutaneously) using a pre-filled syringe device. A nurse or doctor will teach you how to use the syringe to inject yourself, and details are also provided in the package insert. Injections are given under the skin of the stomach, thighs or upper outer arms.

You will be provided with a special bin so that you can dispose of your syringes safely.

Risankizumab must be stored in a refrigerator (between 2 to 8°C). When travelling with your this treatment, you should have a cool box or cool bag with icepacks to maintain the recommended temperature. Once risankizumab has been removed from the refrigerator and has reached room temperature (up to 25°C) it must either be used or thrown away as there is currently no information on how long it can be kept at room temperature – it should not be put back in the fridge.

How often should risankizumab be taken?

Each syringe or pen contains either 75 mg or 150 mg of risankizumab. Therefore, depending on which syringe or pen you have been given, you will need to inject either:

- TWO injections of 75 mg (total dose 150 mg) for the first dose, then another TWO injections of 75 mg 4 weeks later, or
- You will need to inject 150 mg for the first dose, then another 150 mg 4 weeks later.

After this you should continue to inject every 12 weeks with either one injection of 150 mg, or two injections of 75 mg. If you respond, this can be continued to maintain long-term control of your psoriasis.

What are the possible side effects of risankizumab?

Most of the side effects reported during clinical trials of risankizumab were mild, easily manageable, and did not require treatment to be stopped.

Mild

- *Reactions at the injection sites* are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your dermatologist.
- *Cold & flu symptoms, sore throat.*
- *Mild fungal infections* such as athlete's foot.
- *Itching* (pruritus).
- *Headache.*
- *Tiredness* (fatigue).

Potentially severe

Serious infections. Risankizumab may decrease your ability to fight infection. Your doctor will ask you about any current or past infections (particularly

tuberculosis), or if you are prone to infections such as cold sores or urinary tract infections. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. Your doctor will also ask if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection or viral hepatitis. It is advisable to avoid close contact with anyone who has a bad cold, influenza or chest infections, and wash your hands frequently during the course of treatment.

Fewer than 1 out of every 100 individuals treated with Risankizumab experience a serious infection in the first 3-4 months of treatment.

Allergic reactions. It is possible that some patients could experience an allergic reaction to risankizumab. Severe reactions requiring emergency treatment are very rare.

Overall, about 1 out of every 100 individuals treated with Risankizumab need to stop their treatment in the first 3-4 months owing to unwanted side effects.

How can the risk of side effects be minimised?

Before you start taking risankizumab, you will have a thorough consultation with your dermatologist/team including a clinical examination and a number of blood tests will be carried out. Additional investigations may be required depending on your medical history (for example, a chest Xray or other imaging).

Your dermatologist will go through the checklist below. These situations do not necessarily mean that treatment with risankizumab cannot be given, but may mean that other precautions are needed for you to have this treatment safely. Your dermatologist would discuss your individual situation and explain more about this.

- *Tuberculosis*, or close contact with someone who has had it.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- *Infection and vaccination history.* If you are scheduled to have *any type of vaccination*.
- If you are scheduled to have *major surgery*.
- If you are *pregnant or breastfeeding* or are *planning a family*.

You are encouraged to take part in any *National Health screening programmes* at the recommended times (e.g. cervical smears and mammograms).

During risankizumab treatment you will be asked about side effects and have blood tests from time to time (for example every 6 months). It is advisable to keep the dermatology team and your GP informed at all times of changes to your medications, planned procedures, and surgery or health problems including:

- *If you get an infection, or any symptom or sign of an infection that doesn't go away*, including fever, lethargy, cough, influenza-like symptoms, burning when passing urine, dental problems, night sweats. Your dermatologist may suggest stopping risankizumab temporarily.
- *If you bruise or bleed very easily*, or look very pale.
- *If you develop signs of a severe allergic reaction, such as a swollen face/tongue, throat tightness or difficulty with breathing (known as anaphylaxis)*, **dial 999 for an ambulance immediately** and go to a hospital Accident and Emergency department. Afterwards ensure the dermatologist has been informed.

What will happen if I need an operation or dental surgery?

Risankizumab comes under the category of an 'immune suppressant' and therefore may increase your risk of getting an infection after a surgical procedure. For planned procedures, you may be advised to stop taking risankizumab prior to the surgery. Please discuss this with your doctor or dentist.

Can I have immunisations (vaccinations) whilst on risankizumab?

Patients on risankizumab should not be given any of the 'live' vaccines such as the *flu vaccine administered through the nose* (because when given this way a live vaccine is used), measles, mumps and rubella (MMR), yellow fever, bacillus Calmette-Guérin bacillus (BCG), rotavirus, oral typhoid, varicella (chickenpox) and herpes zoster (shingles). If you require immunisation with a live vaccine, risankizumab should be stopped for at least 21 weeks before (12 months in the case of shingles vaccine) and until 4 weeks after the vaccination. You should discuss this with your dermatologist.

'Inactivated' (not live) vaccines (e.g. Pneumovax and the *annual flu vaccine administered by injection*) are safe and recommended.

However, it is important to always check with the healthcare professional when having a vaccination and make them aware that you are on risankizumab.

For more detailed information see the British Association of Dermatologists patient information leaflet on [Immunisations](#)).

Does risankizumab affect pregnancy?

We do not know the effect risankizumab has on conception (getting pregnant), on the developing baby or in breastfed babies, and so pregnancy and breastfeeding should be avoided during risankizumab treatment. The effect of risankizumab continues for some time after stopping the treatment, so it is important that this is taken into account. If you are pregnant or are planning to become pregnant, please discuss this with your dermatologist as they will be able to advise on your individual circumstances.

Travelling abroad while taking risankizumab

If travel abroad is planned, please discuss this with the dermatologist. Depending on where you are travelling, precautions may need to be taken against infections.

May I drink alcohol while taking risankizumab?

There is no known interaction between alcohol and risankizumab.

Can I take other medicines at the same time as risankizumab?

Most medicines are safe to take with risankizumab. However, it is important that your GP and other doctors are aware that you are taking it.

The BAD Biologic Interventions Register (BADBIR)

Because risankizumab treatment for psoriasis is relatively new, you may be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use risankizumab and similar drugs. No information will be recorded on the register without your informed consent.

Where can I get more information about risankizumab?

References:

[British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update](#)

This information sheet does not list all of the side effects of risankizumab. If you wish to find out more about risankizumab please speak to your doctor, specialist nurse or pharmacist.

For further details, look at the drug information sheet which comes as an insert with your prescription for risankizumab.

Or visit the emc website to view the patient information leaflet online

<https://www.medicines.org.uk/emc/product/10199/pil>

Or visit the website <https://www.skyrizi.com/>

The Psoriasis Association

<https://www.psoriasis-association.org.uk/>

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

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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