PATIENT INFORMATION LEAFLET

BIMEKIZUMAB

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about bimekizumab. 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 BIMEKIZUMAB AND HOW DOES IT WORK?

Bimekizumab is a medicine called a biologic. It is used to treat skin conditions that cause inflammation, like psoriasis and hidradenitis suppurativa.

Biologic medicines are made using living cells and are designed to work with the body's immune system.

Bimekizumab works by blocking certain chemical messengers in the body – these are called cytokines. Specifically, it targets two cytokines known as IL-17A and IL-17F.

These messengers play a big part in causing inflammation. By blocking them, bimekizumab stops the inflammation.

WHAT SKIN CONDITIONS ARE TREATED WITH BIMEKIZUMAB?

Bimekizumab is licensed to treat inflammatory skin conditions. These include:

- psoriasis
- hidradenitis suppurativa (not available on the NHS for this condition)

Psoriatic arthritis is a type of arthritis that can be linked with psoriasis and can also be treated with bimekizumab.

WHY HAVE I BEEN SELECTED FOR TREATMENT WITH BIMEKIZUMAB?

Bimekizumab is licensed for those who need treatment according to national guidelines. Usually, this is because:

- your condition has not improved with other treatments such as creams or ointments,
- or there may be safety reasons why you cannot receive other treatments.

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

Bimekizumab does not work immediately and can take up to 3 months to see the full benefit. In clinical trials, more than 5 out of 10 people were clear or nearly clear of psoriasis by 3 months.

If you are taking bimekizumab for another skin condition, then your doctor can give you more information on when you can expect to see a benefit.

HOW DO I TAKE BIMEKIZUMAB?

Bimekizumab is given as two injections under the skin. This method is called subcutaneous injection. The medicine comes in either a pre-filled syringe or a pen device.

A nurse or doctor will teach you how to use the appropriate device to inject yourself. The details are also given in the package leaflet. Injections are made under the skin of the stomach, thighs or upper outer arms.

A special bin will be provided so that the syringe or pen can be disposed safely.

Bimekizumab must be stored in a refrigerator (between 2 to 8°C). Once removed from the refrigerator and stored at room temperature (up to 25°C), it must be kept out of direct

sunlight. Bimekizumab must be discarded after 25 days, or by the expiry date printed on the container, whichever comes first.

When travelling with the medication, you should have a cool box or cool bag with icepacks to maintain the recommended storage temperature.

HOW SHOULD I TAKE BIMEKIZUMAB?

Psoriasis

- For the first five doses, you will need to inject 320 mg of bimekizumab every 4 weeks up to week 16, and then every 8 weeks to maintain your skin. The dose of bimekizumab can be given either as:
    - two subcutaneous injections of 160 mg, or
    - one subcutaneous injection of 320 mg.
- For some patients, a higher dose may be considered depending on their weight and their response to treatment.
- If the treatment is effective, in can be continued as part of the long-term control of your psoriasis.

Hidradenitis suppurativa

- To begin with, you will need to inject 320 mg of bimekizumab every 2 weeks up to week 16, and then every 4 weeks to maintain your skin. The dose of bimekizumab can be given either as:
    - two subcutaneous injections of 160 mg, or
    - one subcutaneous injection of 320 mg.
- If the treatment is effective, it can be continued as part of the long-term control of your hidradenitis suppurativa.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF BIMEKIZUMAB?

Most side effects reported in clinical trials for bimekizumab were:

- mild
- easily manageable
- 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 these symptoms around the injection site do not go away, or get worse, contact your dermatologist.

Other symptoms could be:

- Cold & 'flu symptoms, sore throat, stuffy nose (nasopharyngitis)
- Stomach 'flu (gastroenteritis), diarrhoea, nausea
- Cold sores (herpes simplex infections)
- Bacterial skin infections (cellulitis)
- Mild fungal infections such as athlete's foot, genital or oral thrush (candidiasis)
- Headaches, rash, hives (urticaria)
- Eye infections (conjunctivitis)

Potentially severe

Fewer than 2 out of every 100 individuals treated with bimekizumab experience a serious adverse effect in the first 3 to 4 months of treatment.

Serious

Fewer than 2 out of every 100 individuals treated with bimekizumab experience a serious side effect in the first 3 to 4 months of treatment.

Serious infections. Bimekizumab may lower your ability to fight infections. Your doctor will ask about any current or past infections (particularly tuberculosis). They will also ask if you are prone to infections, such as cold sores, candida (thrush) or urinary tract infections. If you develop any symptoms of tuberculosis (dry cough that does not go away, weight loss, fever, night sweats) call your doctor.

Your doctor will also ask if you have had any illness that affects your immune system. These can include cancer, human

immunodeficiency virus (HIV) infection or viral hepatitis.

While taking bimekizumab, try to stay away from people who have a bad cold, the 'flu, or a chest infection. It is also important to wash your hands often, to avoid catching infections.

Blood problems. Some patients in the clinical trials had problems producing enough of the blood cells that help to fight infections or stop bleeding.

Allergic reactions. It is possible that some patients could experience an allergic reaction to bimekizumab. Severe reactions requiring emergency treatment (for example, anaphylaxis) are very rare.

HOW CAN THE RISK OF SIDE EFFECTS BE REDUCED?

Before taking bimekizumab

Your dermatologist will talk to you and do a careful check-up. This includes a clinical examination and some blood tests. Depending on your health history, you might need more tests, such as a chest X-ray or other imaging.

Your dermatologist will go through a safety checklist with you. Just because something is on the list does not mean you cannot take bimekizumab. – It might mean extra care is needed to make sure the treatment is safe for you.

Your dermatologist will talk with you about your personal health and explain everything clearly. They may ask:

- If you have had tuberculosis or been in close contact with someone who has.
- If you have had hepatitis or HIV, or if you think you might be at risk.
- Your infection and vaccination history, and if you are due to have any vaccines.
- If you have had an inflammatory bowel disease, such as Crohn disease or ulcerative colitis.
- If you are scheduled to have a major surgery.
- If you are pregnant or breastfeeding or are planning to have a baby.

You are encouraged to take part in any National Health screening programmes at the routine time points recommended (e.g. cervical smears, mammograms).

During your treatment with bimekizumab

You will be asked about side effects. You will also have blood tests from time to time (for example every 6 months) at your clinic appointments. Keep your doctor or dermatology team informed of any 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 does not go away. This includes:
    - fever
    - lethargy
    - cough
    - flu-like symptoms
    - burning on passing urine
    - dental problems
    - night sweats.

In these cases. your dermatologist may suggest stopping bimekizumab temporarily.

- If you bruise or bleed very easily or look very pale.
- Dial 999 for an ambulance immediately and go to an Accident and Emergency department if you develop signs of a severe allergic reaction, such as:
    - a swollen face/tongue
    - throat tightness
    - or difficulty with breathing (known as anaphylaxis).

Afterwards, you should make sure that your dermatologist has been informed.

WHAT WILL HAPPEN IF I NEED AN OPERATION OR DENTAL SURGERY?

Bimekizumab is a medicine that lowers the body's immune system. This means your body might not fight off infections as well, especially after surgery (for example, an operation or a tooth extraction).

For planned procedures, it is important to tell your doctor, surgeon, dentist, and dermatology team that you are taking bimekizumab. They may advise you to stop taking the medicine before the procedure.

CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON BIMEKIZUMAB?

People who receive bimekizumab treatment should not get vaccinated with 'live' vaccines.

These include:

- the 'flu vaccine administered through the nose
- measles, mumps and rubella (MMR)
- yellow fever
- bacillus Calmette-Guẻrin bacillus (BCG)
- rotavirus
- oral typhoid
- varicella (chickenpox)

Bimekizumab should be stopped for at least 12 months before getting any vaccination. You should then wait for 4 weeks after the vaccination before you can restart bimekizumab treatment. You will be able to discuss this further with your dermatology team.

'Inactivated' or non-live vaccine injections, such as those listed below, are safe and recommended.

- Pneumovax®
- Shingrix® (for shingles)
- the annual 'flu
- Covid-19

However, you should always check with your healthcare professional when having a vaccination and inform them that you are on bimekizumab.

DOES BIMEKIZUMAB AFFECT PREGNANCY?

Right now, we do not know enough about how bimekizumab might affect if you are trying to get pregnant, the pregnancy itself, or babies who are breastfed. This is why pregnancy and breastfeeding should be avoided while taking the medicine.

If you are planning for pregnancy, please discuss with your dermatologist. They will be able to advise on your individual circumstances.

If bimekizumab is used in the later stages of pregnancy, it might affect the baby's immune system for up to six months after birth. For this reason:

- a baby born to a mother who has received bimekizumab during pregnancy from 16 weeks or more after conception, should not receive any live vaccines in the first 6 months after birth.
- However, non-live vaccines can be given safely.
- Breast feeding should be discussed with your dermatologists.

CAN I TRAVEL ABROAD WHILE TAKING BIMEKIZUMAB?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on where you are travelling, you may need to take precautions against infections. Depending on the length of your travel plans, you may need a cool box to take the medication with you.

MAY I DRINK ALCOHOL WHILE TAKING BIMEKIZUMAB?

There is no known interaction between alcohol and bimekizumab.

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

Most medicines are safe to take with bimekizumab. However, it is important that your GP and other doctors are aware that you are taking it, especially if any new drugs are prescribed.

Your GP and dermatologist should be aware of all your medications. These include over-the-counter medicines and supplements, including herbal medicines.

The BAD Biologic Interventions Register (BADBIR)

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

WHERE CAN I GET MORE INFORMATION ABOUT BIMEKIZUMAB?

If you wish to find out more about bimekizumab please speak to your doctor, specialist nurse or pharmacist.

The patient information insert in the packaging provides further information about bimekizumab. Alternatively, visit the electronic medicines compendium (emc) website www.medicines.org.uk/emc/product/8199/pil to view the patient information online.

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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