



A GUIDE FOR PATIENTS PRESCRIBED VECTIBIX® (PANITUMUMAB)

This booklet is only intended for patients who have been prescribed Vectibix®

The information on this booklet is not intended as a substitute for consultation with your healthcare professional.

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WELCOME TO VECTIBIX® (PANITUMUMAB)

Your doctor, nurse, or healthcare provider has given you this booklet because you are being treated with a medication called Vectibix® (panitumumab) for the treatment of adult metastatic colorectal cancer (bowel cancer).

This booklet aims to provide some answers to the following questions:

- What is metastatic colorectal cancer and how is it treated?
- What is Vectibix® and how does it work?
- How is Vectibix® administered?
- What are the possible side effects of Vectibix®?
- Is there anything else to consider when taking Vectibix®?

Please also read the patient information leaflet (PIL) for this medicine. If you do not have a copy, your doctor or nurse should be able to provide one or you can access it at www.medicines.ie/medicines/vectibix-34143/patient-info.

- Visit the patient website www.amgencare.ie to see more information about Vectibix®.

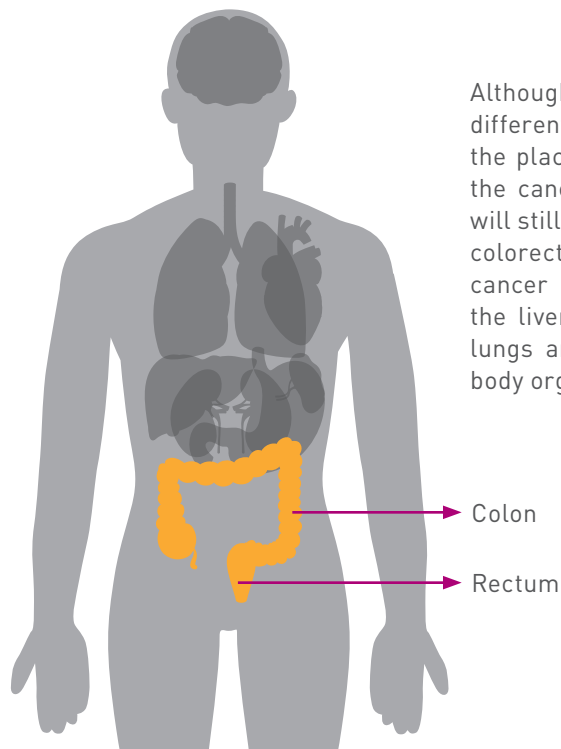
If you have any questions, or feel unsure about any aspect of your treatment, please speak to your doctor, nurse or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

WHAT IS METASTATIC COLORECTAL CANCER (mCRC)?

Colorectal cancer, also known as 'bowel cancer', is a cancer that starts in the large intestine (colon or rectum). These cancers can also be called colon cancer or rectal cancer, depending on where they start.¹ It is called 'metastatic' when cancer cells spread to other parts of the body and form a new tumour or 'metastasis'.²



Although the cancer may now be in a different organ, it is still named after the place where it originated. So, if the cancer spreads to the lungs, it will still be referred to as metastatic colorectal cancer.² Colon or rectal cancer most commonly spreads to the liver. It can also spread to the lungs and bones, as well as other body organs.³

HOW IS mCRC TREATED?

Your medical team will assess your case carefully. They will develop a personalised treatment plan, which may include chemotherapy, and/or targeted therapy, and/or surgery.⁴ This treatment plan will depend on⁴:

- Where the tumours are in your body.
- How accessible the tumours are to surgery.
- Your general health, your medical history, recent blood tests and well-being.
- Other aspects of the cancer.

The type of treatment that is recommended by your doctor will aim to meet your specific needs. Usually, treatment will consist of chemotherapy that may be used in combination with targeted therapy. It is possible that your treatment may not be continuous:

- Chemotherapy may be started then stopped and restarted later, sometimes in combination with other drugs, which is intended to give you the best possible quality of life and minimise the side effects you experience.⁵

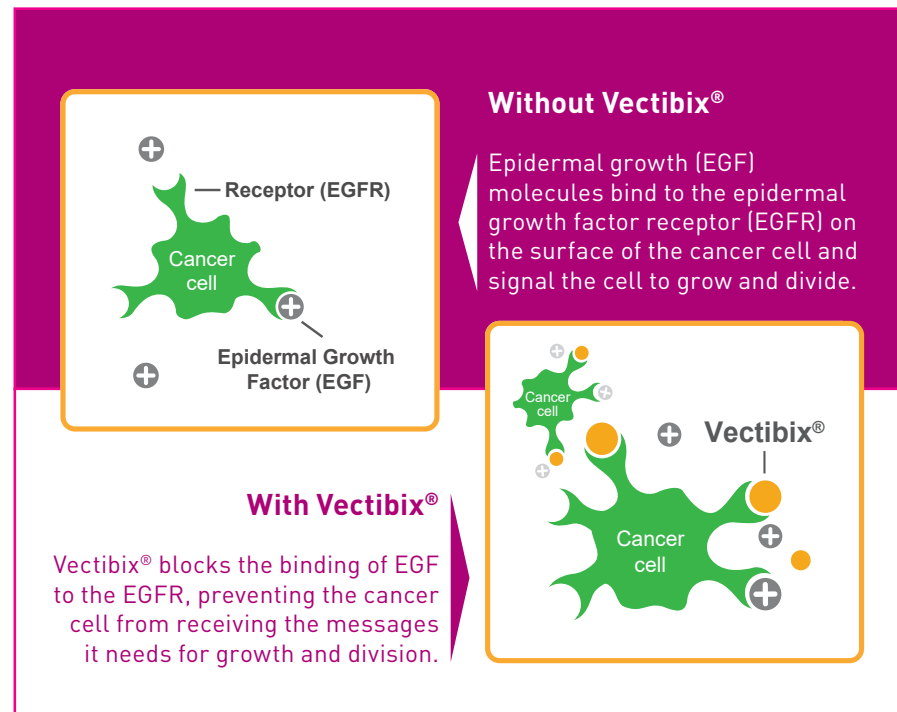


WHAT IS VECTIBIX® AND HOW DOES IT WORK⁶?

Vectibix® is used for the treatment of metastatic colorectal cancer for adult patients with a type of tumour known as 'wild type RAS tumour'. A test is done to confirm that you have this type of tumour.

This medicine contains the active substance panitumumab, a type of medicine known as a monoclonal antibody. Monoclonal antibodies are often referred to as targeted therapies, because they target specific protein receptors within or on the surface of cells that are involved in the spreading and growth of the cancer cells.⁷

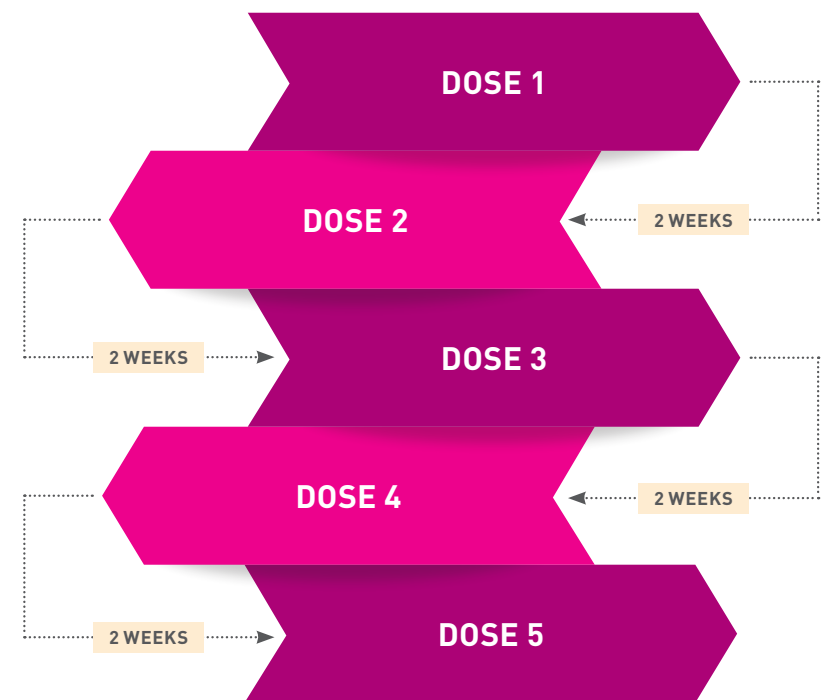
Vectibix® works by attaching itself to the epidermal growth factor receptors (EGFR) found on the surface of some cancer cells. By doing this, Vectibix® blocks epidermal growth factor (EGF) from attaching to the cancer cell. If EGF can't attach, the cancer cell can't receive the messages it needs to grow and divide. Vectibix® is therefore classed as an EGFR Inhibitor.



HOW IS VECTIBIX® ADMINISTERED^{6,8}?

Vectibix® is a colourless liquid and is given by infusion into a vein (a drip). You will need to go to hospital to have this medicine. Vectibix® infusions are given once every two weeks.

Vectibix® is given using an infusion pump - a device which gives a slow infusion. The first infusion may take between 60 and 90 minutes. If your doctor advises, future infusions can be given more quickly, taking between 30 and 60 minutes.



Vectibix® may be used alone or in combination with other anticancer medicines.

You will have a blood test before starting treatment and regularly during treatment with this medicine.

Usually, Vectibix® treatment is continued for as long as it is helping you and the side effects aren't too severe or life threatening.⁹



WHAT ARE THE POSSIBLE SERIOUS SIDE EFFECTS OF VECTIBIX®?

Like all medicines, Vectibix® can cause side effects. Everyone is different, so some people experience very few, if any side effects, while others may experience more. Some may be mild and some may be more severe. If you experience any side effects, talk to your doctor or nurse who will be able to recommend ways to prevent or limit the side effect.

Some serious side effects of Vectibix® include:

ALLERGIC REACTIONS

Very rarely, serious allergic (hypersensitivity) reactions involving symptoms similar to an infusion reaction (see "Infusion reactions" in the next page) have occurred more than 24 hours after treatment and resulted in a fatal outcome. Seek medical attention immediately if you experience symptoms of an allergic reaction to Vectibix®, including but not limited to difficulty breathing, chest tightness, a sensation of choking, dizziness, or fainting.

SKIN REACTIONS

Skin-related reactions are likely to occur in approximately 94 out of 100 people who take Vectibix® and are usually mild to moderate.

The skin rash commonly resembles acne and often involves the face, upper chest and back, but can affect any area of the body. Some rashes have been associated with redness, itching and flaking of the skin which can become severe. In some cases, it may cause infected sores requiring medical and/or surgical treatment, or cause severe skin infections that in rare cases could be fatal. In rare cases patients may experience blistering of the skin, mouth, eyes and genitals, which may indicate a severe skin reaction called "Stevens-Johnson syndrome" or blistering of the skin, which may indicate a severe skin reaction called "toxic epidermal necrolysis". If you experience blistering, you should notify your doctor immediately. Prolonged exposure to the sun can make the rash worse. Also, dry skin, fissures (cracks in the skin) on the fingers or toes, fingernail bed or toenail bed infection (paronychia) or inflammation has been reported. Once treatment is withheld or discontinued, the skin reactions will generally resolve. Your doctor may decide to treat the rash, adjust the dose or discontinue your treatment with Vectibix®.

For more information on skin reactions please refer to page 13 of this booklet.

INFUSION REACTIONS

During or following treatment you may experience an infusion reaction. These can be mild or moderate (likely to occur in approximately 5 out of 100 people who take Vectibix®), or severe (likely to occur in 1 out of 100 people who take Vectibix®).

Symptoms may include:

- Headache
- Rashes
- Itching or hives
- Flushing
- Swelling (face, lips, mouth, around the eyes, and throat area)
- Rapid and irregular heartbeat
- Fast pulse
- Sweating
- Nausea
- Vomiting
- Dizziness
- Difficulty breathing or swallowing
- Decrease in blood pressure that may be severe or life-threatening and, very rarely, may lead to death

If you experience any of these symptoms, you should notify your doctor immediately. Your doctor may decide to reduce the rate of your infusion or discontinue your treatment with Vectibix®.

WHAT OTHER SIDE EFFECTS COULD YOU EXPECT WITH VECTIBIX®?

The main very common and common possible side effects for Vectibix® are listed below.

Please note that THIS IS NOT A FULL LIST OF POSSIBLE SIDE EFFECTS, WARNINGS AND PRECAUTIONS.

Please refer to the Patient Information Leaflet available on www.medicines.ie/medicines/vectibix-34143/patient-info for a complete list of possible uncommon side effects (may affect up to 1 in 100 people). **If you have any questions or concerns about side effects, please talk to your doctor, nurse or pharmacist.**

Very common: may affect more than 1 in 10 people
<ul style="list-style-type: none"> low red blood cell numbers (anaemia); low potassium levels in the blood (hypokalaemia); low magnesium levels in the blood (hypomagnesaemia);
<ul style="list-style-type: none"> eye inflammation (conjunctivitis);
<ul style="list-style-type: none"> local or widespread rash which may be bumpy (with or without spots), itchy, red or flaky;
<ul style="list-style-type: none"> hair loss (alopecia); mouth ulcers and cold sores (stomatitis); inflammation of the mouth (mucosal inflammation);
<ul style="list-style-type: none"> diarrhoea; nausea; vomiting; abdominal pain; constipation; decreased appetite; decreased weight;
<ul style="list-style-type: none"> extreme tiredness (fatigue); fever or high temperature (pyrexia); lack or loss of strength (asthenia); accumulation of fluid in the extremities (oedema peripheral);
<ul style="list-style-type: none"> back pain;
<ul style="list-style-type: none"> inability to sleep (insomnia);
<ul style="list-style-type: none"> cough; dyspnoea (breathing difficulties).

(continued on next page)

Common: may affect up to 1 in 10 people

- low white blood numbers (leucopenia); low calcium levels in the blood (hypocalcaemia); low phosphates in the blood (hypophosphataemia); high glucose in the blood (hyperglycaemia);
- growth of eyelashes; flow of tears (lacrimation increased); redness of the eye (ocular hyperaemia); dry eye; itchy eyes (eye pruritus); eye irritation; eyelid inflammation (blepharitis);
- skin ulcer; scab; excess hair growth (hypertrichosis); redness and swelling of palms of hands or soles of feet (hand-foot syndrome); excess sweating (hyperhidrosis); skin reaction (dermatitis);
- spreading infection below the skin (cellulitis); hair follicle inflammation (folliculitis); localised infection; skin rash with pus-filled blisters (rash pustular); urinary tract infection;
- nail disorder; breaking of the nails (onychoclasia);
- dehydration;
- dry mouth; indigestion (dyspepsia); rectal bleeding (rectal haemorrhage); lip inflammation (cheilitis); heartburn (gastroesophageal reflux);
- chest pain; pain; chills; pain in the extremity; immune reaction (hypersensitivity); rapid heart rate (tachycardia);
- blood clot in the lung (pulmonary embolism) the symptoms of which may be sudden onset of shortness of breath or chest pain; nose bleed (epistaxis); blood clot in a deep vein (deep vein thrombosis); high blood pressure (hypertension); flushing;
- headache; dizziness; anxiety.

Do not use Vectibix®:

- if you are allergic to panitumumab or any of the other ingredients of this medicine (sodium chloride, sodium acetate trihydrate, acetic acid (glacial) and water for injections).
- if you have previously had or have evidence of interstitial pneumonitis (swelling of the lungs causing coughing and difficulty breathing) or pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath).
- in combination with oxaliplatin-based chemotherapy, if your RAS test shows that you have mutant RAS tumour, or if your RAS tumour status is unknown. Please consult your doctor if you are unsure of your RAS tumour status.

IS THERE ANYTHING ELSE TO CONSIDER WHEN TAKING VECTIBIX®⁶?

Eyes

Tell your doctor if you use contact lenses and/or have a history of eye problems such as severe dry eye, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye.

If you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment.

Other medicines

It is important to tell your doctor or nurse about any other medication you are taking. This includes vitamins, herbal supplements and over the counter medicines. Some drugs do not work well together, so it is important that you discuss this with your doctor or nurse before starting treatment.

When you are being treated with Vectibix®, it is advisable not to take any additional medicines without first checking with your healthcare team.

Pregnancy and breast-feeding

Vectibix® has not been tested in pregnant women. It is important to tell your doctor or nurse if you are pregnant; think you may be pregnant; or plan to get pregnant. Vectibix® could affect your unborn baby or ability to stay pregnant.

If you are a woman of child bearing potential, you should use effective methods of contraception during treatment with Vectibix® and for 2 months after the last dose.

It is not recommended to breastfeed your baby during treatment with Vectibix® and for 2 months after the last dose. It is important to tell your doctor if you plan to breastfeed.

Driving and using machines

You should speak with your doctor before driving or using machines, as some side effects may impair your ability to do so safely.

WHAT SKIN REACTIONS SHOULD I LOOK OUT FOR⁶?

Approximately 94 out of 100 people experience skin reactions while receiving treatment with Vectibix®. These are usually mild to moderate reactions that resolve after treatment discontinuation and which may or may not affect your quality of life on treatment. **If you experience skin reactions or severe swelling tell your nurse or doctor as soon as possible so that they can take the necessary action.** Even if these changed or cleared up before an appointment, it is still important that you mention them to your healthcare provider so that the side effects you have can be recorded.

The next pages contain photos and information to help you identify whether you are experiencing some of these more common side effects. Being able to recognise and describe side effects to your healthcare provider can help them determine how to best manage your treatment. **These photos are just examples of how skin-related side effects can look. Having side effects doesn't always mean that your treatment will change.**

The photos on the next pages are provided as an example. Appearance may vary in different patients, not all patients will experience the same adverse events. Severity may also vary.



Skin rash (Acneiform rash)¹⁰



MILD

MODERATE

SEVERE



MILD

MODERATE

SEVERE

What is it?

- A rash on the face or body, appearing as soon as 2–3 days after each treatment
- This is not a form of acne though it may look similar
- The pictures above show the condition at different levels of severity

Looks like:

- Often appears on the face or upper body
- Rashes begin as small bumps or swollen areas that resemble pimples
- Bumps have a flat shape and fill with pus before eventually drying out and developing a yellow crust
- Sun exposure can worsen the rash⁸

Feels like:

- Can be itchy and may result in loss of skin when scratched

The photographs in this page have been kindly provided with permission from Professor Siegfried Segaert, MD, PhD, Professor in Dermatology at the University Hospital in Leuven, Belgium.

Dry skin conditions (Xerosis)^{10, 11, 12}



MODERATE

What is it?

- Conditions that cause red and inflamed skin that can be very dry
- Caused by the loss of naturally occurring, protective oils on the skin's surface
- Also known as 'winter eczema', as it's common in winter months when the air is drier
- The picture above shows a moderately severe form of the condition

Looks like:

(One or more of the following)

- Skin that is red, swollen, and cracked
- Skin that is crusty, scaly, or releasing a clear fluid
- Patches of dry skin that are red to dark brown
- Skin that has become thick and hard
- Often appears on arms and legs, but can appear anywhere affected by acneiform rash

Feels like:

(One or more of the following)

- Can be extremely itchy
- Can be inflamed and irritated

The photographs in this page have been kindly provided with permission from Professor Siegfried Segaert, MD, PhD, Professor in Dermatology at the University Hospital in Leuven, Belgium.

Split skin (Fissures)¹⁰

What is it?

- Dry skin that leads to cracks on the fingers and toes
- The picture on the left shows the condition at a moderate severity



MODERATE

Looks like:

(One or more of the following)

- Paper cut-like cracks on the fingertips, knuckles, in the nail folds, and on the heels of the feet
- Fingernails become brittle and grow more slowly

Feels like:

(One or more of the following)

- Can be painful to the touch
- Can lead to difficulty performing everyday tasks

Nail changes (Paronychia)¹⁰



MILD



MODERATE



SEVERE

What is it?

- Inflammation of the nail fold that can result in infection
- The pictures above show the condition at different levels of severity

Looks like:

- Redness and inflammation around the fingernails and toenails

Feels like:

(One or more of the following)

- Can be very painful to the touch, similar to an ingrown toenail
- Can affect people's ability to perform everyday tasks

Overgrowth of eyelashes (Trichomegaly)¹⁰

What is it?

- Excessive growth of the eyelashes
- Can contribute to an eye infection

Looks like:

- Eyelashes that grow very long, rigid, and curly

Feels like:

- Dryness or irritation in eye area



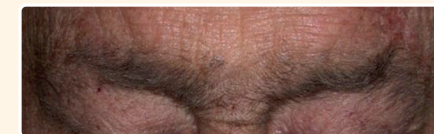
Overgrowth of face and body hair (Hypertrichosis)¹⁰

What is it?

- Excessive growth of face and body hair

Looks like:

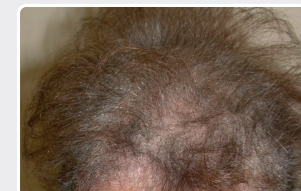
- Eyebrows that grow thicker and more pronounced
- Eyebrows can grow to meet in the centre of the face or extend to the sides of the eye area



Thinning of hair (Alopecia)¹⁰

What is it?

- Thinning of the hair
- The pictures to the right show the condition at different levels of severity



MILD



MODERATE

Looks like:

(One or more of the following)

- Scalp and body hair grows more slowly, with a fine, brittle, and curly texture
- Mild hair loss on the arms and legs

The photographs in these pages have been kindly provided with permission from Professor Siegfried Segaert, MD, PhD, Professor in Dermatology at the University Hospital in Leuven, Belgium.

WHEN STARTING TREATMENT WITH VECTIBIX[®], HOW SHOULD I LOOK AFTER MY SKIN AND NAILS?



Follow the Advice Given by your Doctor or Nurse

Contact your doctor or nurse right away if you experience rash or any other side effects, as these can be managed if they are recognised and treated early.



Avoid the Sun

- Avoid direct sun exposure as much as possible and wear a sunscreen with Sun Protection Factor (SPF) higher than 15. Ideally you should wear sunscreen with SPF that is as high as possible for any time spent outdoors, even on a cloudy day.¹³
- Apply sunscreen to your face and on any sun-exposed areas such as your chest, arms and back and re-apply sunscreen every 2 hours or more frequently if sweating or swimming.¹⁴
- Use a broad-brimmed hat and long sleeved T-shirt when going outside.^{10,14}



For your Finger and Toe Nails

- Avoid pushing back cuticles or biting out nails.¹³
- Do not use artificial nails.
- Use a nail file instead of cutting nails and cotton-lined gloves when washing dishes or cleaning.
- Do not wear tight shoes.^{10,13}
- Please consult your doctor or nurse before going to a chiropodist.
- If there are any changes to your nails please consult your doctor or nurse.



For your Skin and Hair

- Use moisturising creams (water-based) on limbs including hands and feet and apply daily.^{10,13}
- Use mild skin care products.^{10,13}
- Use tepid water when showering or bathing.^{10,13}
- When rubbing cream in, do so in the direction of the hair.
- Use a gentle or anti-dandruff shampoo and leave for three minutes and wash off.¹⁵
- Use an electric razor as this is less traumatic on the skin. If wet shaving is preferred use a gentle wash such as E45 instead of shaving foam.¹⁵
- If you experience trichomegaly (long, curly, rigid eyelashes) and are able you can trim your eyelashes on a regular basis; if you are unable to do this, you may need to see an eye doctor.¹⁰
- Use mild soaps when cleansing the skin and avoid harsh laundry detergent with strong perfume.^{14,16}
- Avoid products which contain additives that may irritate your skin such as perfumes, dyes or alcohol.¹⁶
- While the acneiform rash may look like acne it is not acne; therefore patients should avoid over-the counter acne products.^{10,13}



VECTIBIX® APPOINTMENT DATES:

Keeping track of your Vectibix® infusions can help you stay organized. It's important to follow the treatment schedule your doctor has prescribed for you.

Clinic contact No:

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IMPORTANT CONTACTS LIST:

Doctor's name:

Nurse's name:

Hospital telephone number:

Out of hours telephone number:

LIST OF SKIN PRODUCTS I CAN USE

Your doctor or nurse can recommend what products you can on your skin and nails.

Product Name	For body	Hands	Face	Nails

TOPICS TO TALK ABOUT IN MY NEXT APPOINTMENT

MY SELF-CARE

Use this page to note down some self-care routines that you find important. Here are some thoughts to get you going:

- Go for a daily walk;
- Talk with friends and family;
- Make time in your day to do something for yourself.

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PLEASE REFER TO THE PATIENT
INFORMATION LEAFLET THAT CAME
WITH YOUR MEDICINE, OR AVAILABLE AT
[www.medicines.ie/medicines/vectibix-34143/
patient-info](http://www.medicines.ie/medicines/vectibix-34143/patient-info)

Visit the patient website www.amgencare.ie for more
information (for quick access, scan the below QR code with your
phone's camera or QR reader app)



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