PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

BASMEDENE 20, 20 mg tablet
Bilastine.
Sugar free.

Read all of this leaflet carefully because it contains important information for you
BASMEDENE 20 is available without a doctor's prescription, for you to treat a mild condition. Nevertheless, you still need to use **BASMEDENE 20** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **BASMEDENE 20** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet
1. What **BASMEDENE 20** is and what it is used for
2. What you need to know before you take **BASMEDENE 20**
3. How to take **BASMEDENE 20**
4. Possible side effects
5. How to store **BASMEDENE 20**
6. Contents of the pack and other information

1. What BASMEDENE 20 is and what it is used for
BASMEDENE 20 is used to help treat and relieve the symptoms of hayfever (sneezing, itchy, runny, blocked nose and red and watery eyes) and other forms of allergic rhinitis. It may also be used to treat itchy skin rashes (hives or urticaria).

2. What you need to know before you take BASMEDENE 20
Do not take BASMEDENE 20
- If you are hypersensitive (allergic) to bilastine or any of the other ingredients of **BASMEDENE 20** (listed in section 6).

Warnings and precautions
Special care should be taken with **BASMEDENE 20**:
- If you have moderate or severe kidney problems.

Children
This medicine is not for children under 12 years of age.

Other medicines and BASMEDENE 20
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
These may include:
- Diltiazem (to treat angina)
- Ciclosporin (avoiding transplant rejection or for autoimmune and allergic disorders, such as atopic dermatitis, psoriasis or rheumatoid arthritis)
- Rifampicin or Erythromycin (antibiotics)
- Ketoconazole (an antifungal medicine)
- Ritonavir (to treat AIDS)

BASMEDENE 20 with food and drink
Do not take **BASMEDENE 20** with food. Take the tablet one hour before food or two hours after food.
Do not take **BASMEDENE 20** with grapefruit juice or other fruit juices. Take that tablet one hour before drinking the fruit juice or two hours after drinking the fruit juice.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines
BASMEDENE 20 can cause drowsiness and dizziness.
It is not always possible to predict to what extent **BASMEDENE 20** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **BASMEDENE 20** affects them.

3. How to take BASMEDENE 20
Do not share medicines prescribed for you with any other person.
Always take **BASMEDENE 20** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is 1 tablet a day.

Take the tablet with a sufficient quantity of water.

Do not take with food, grapefruit juice or fruit juice. (see section 2)

Do not chew the tablet.

Take **BASMEDENE 20** once a day, every day, at about the same time each day.

If you take more BASMEDENE 20 than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BASMEDENE 20
Do not take a double dose to make up for forgotten individual doses.
If you forgot to take your dose on at your normal time, take it as soon as possible and then go back to your normal time of taking your dose.

4. Possible side effects
BASMEDENE 20 can have side effects.

Not all side effects reported for **BASMEDENE 20** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BASMEDENE 20**, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using **BASMEDENE 20** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Difficulty in breathing, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin, dizziness, collapsing or losing consciousness.

These are all very serious side effects. If you have them, you may have had a serious reaction to **BASMEDENE 20**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
- Headache
- Tiredness
- Drowsiness
- Dizziness
- Stomach pain
- Increased appetite
- Anxiety
- Feeling of weakness
- Irregular heartbeat
- Nausea
- Increased weight
- Diarrhoea
- Dry nose
- Fever
- Cold sores
- Dry mouth
- Thirst
- Itching
- Ringing in ears
- Difficulty sleeping
- Difficulty breathing
- Indigestion
- Vomiting
- A spinning sensation
- A change in the heart's electrical signal (seen on ECG)
- A heart rhythm change (seen on ECG)
- Inflammation of the stomach lining (gastritis)
- Raised liver enzymes (seen on blood tests)
- Changes in kidney function (creatinine) (seen on blood tests)
- Increased blood fat levels (triglycerides) (seen on blood tests)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of **BASMEDENE 20**.

5. How to store BASMEDENE 20
Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package/ container.
- Keep the container in the outer carton.
- Protect from light / moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What BASMEDENE 20 contains
- The active substance is bilastine.

The other ingredients are colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

What BASMEDENE 20 looks like and contents of the pack
White to off white, scored oval shaped tablets debossed with '2' on one side of breakline and '0'on other side of breakline on one side, plain on other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
Plain cold formable Alu foil – 0.025 mm Alu hard tempered foil blister pack. Each blister strip contains 7 or 10 tablets. Blister strips are packed in cardboard boxes.
Pack sizes: 7, 10, 14, 20, 28, 30, 40, 50, 56 or 60 tablets. Not all pack sizes will be marketed.

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This leaflet was last revised in
14 October 2025

Registration number
56/5.7.1/0591

Access to the corresponding Professional Information
www.trinitypharma.co.za

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S2

BASMEDENE 20, 20 mg tablet
Bilastien.
Suikervry.

Lees hierdie hele pamflet deeglik deur, aangesien dit belangrike inligting vir u bevat
BASMEDENE 20 is sonder 'n doktersvoorskrif beskikbaar, sodat u 'n ligte siekte kan behandel. U sal nogtans **BASMEDENE 20** met sorg moet gebruik om die beste resultate daarmee te behaal.
- Hou hierdie pamflet. Dit is moontlik dat u dit weer sal wil lees.
- Moet nie **BASMEDENE 20** met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat in hierdie pamflet is

1. Wat **BASMEDENE 20** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **BASMEDENE 20** neem
3. Hoe om **BASMEDENE 20** te neem
4. Moontlike newe-effekte
5. Hoe om **BASMEDENE 20** te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat BASMEDENE 20 is en waarvoor dit gebruik word
BASMEDENE 20 word gebruik om die simptome van hooikoors (nies, jeukerige, loopneus, toe neus en rooi en waterige oë) en ander vorme van allergiese rinitis te behandel en te verlig. Dit kan ook gebruik word om jeukerige veluitslag (korwe of urtikarie) te behandel.

2. Wat u moet weet voordat u BASMEDENE 20 neem
Moet nie BASMEDENE 20 neem
- Indien u hipersensitief (allergies) is vir bilastien of enige van die ander bestanddele van **BASMEDENE 20** (gelys in afdeling 6.)

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet geneem word met **BASMEDENE 20**:
- Indien u matige of ernstige nierprobleme het.

Kinders
Hierdie medisyne is nie vir kinders onder 12 jarige ouderdom nie.

Ander medisyne en BASMEDENE 20
Noem altyd aan u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit komplimentêre of tradisionele medisyne in.)
Dit kan insluit:
- Diltiasem (vir die behandeling van angina)
- Siklosporien (om oorplantingsverwerping te voorkom of vir outo-immuun- en allergiese afwykings, soos atopiese dermatitis, psoriase of rumatoïede artritis)
- Rifampisien of Eritromisien (antibiotika)
- Ketokonasool ('n antifungale medisyne)
- Ritonavir (vir die behandeling van VIGS)

BASMEDENE 20 met voedsel en drank
Moet nie **BASMEDENE 20** saam met voedsel neem nie**.** Neem die tablet een uur voor voedsel of twee ure na voedsel.
Moet nie **BASMEDENE 20** saam met pomelosap of ander vrugtesappe neem nie**.** Neem die tablet een uur voor u vrugtesap drink of twee ure nadat u vrugtesap gedrink het.

Swangerskap en borsvoeding
Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjinerie
BASMEDENE 20 kan lomerigheid en duiseligheid veroorsaak.
Dit is nie altyd moontlik om te voorspel tot watter mate **BASMEDENE 20** pasiënte se daaglikse aktiwiteite mag beïnvloed nie. Pasiënte moet toesien dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waarin **BASMEDENE 20** hulle affekteer nie.

3. Hoe om BASMEDENE 20 te neem
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem **BASMEDENE 20** altyd presies soos in hierdie pamflet beskryf word of soos u dokter, apteker of verpleegster vir u gesê het. Raadpleeg u dokter, apteker of verpleegster indien u nie seker is nie.

Die gewone dosis is 1 tablet per dag.

Neem die tablet met 'n voldoende hoeveelheid water.

Moet nie saam met voedsel, pomelosap of vrugtesap neem nie. (sien afdeling 2)

Moet nie die tablet kou nie.

Neem **BASMEDENE 20** een keer per dag, elke dag, op ongeveer dieselfde tyd elke dag.

Indien u meer BASMEDENE 20 neem as wat u moet
In geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om BASMEDENE 20 te neem
Moet nie 'n dubbele dosis neem om vergete individuele dosisse op te maak nie.
Indien u vergeet het om u dosis op u normale tyd in te neem, neem dit so gou as moontlik en gaan dan terug na u normale tyd om u dosis in te neem.

4. Moontlike newe-effekte
BASMEDENE 20 kan newe-effekte hê.

Nie alle newe-effekte wat vir **BASMEDENE 20** gerapporteer is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of indien u onaangename effekte ervaar tydens die gebruik van **BASMEDENE 20**, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, stop om **BASMEDENE 20** te neem / gebruik en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling in u naaste hospitaal:

- Moeilike asemhaling, swelling van u gesig, lippe, tong of keel, en/of swelling en rooiheid van die vel, duiseligheid, ineenstorting of bewussynsverlies.

Hierdie is almal baie ernstige newe-effekte. Indien u dit ondervind, het u moontlik 'n ernstige reaksie teen **BASMEDENE 20**. U mag dalk dringende mediese hulp of hospitalisasie benodig.

Vertel u dokter indien u enige van die volgende opmerk:
- Hoofpyn
- Moegheid
- Slaperigheid
- Duiseligheid
- Maagpyn
- Verhoogde eetlus
- Angs
- Gevoel van swakheid
- Onreëlmatige hartklop
- Naarheid
- Gewigstoename
- Diarree
- Droë neus
- Koors
- Koorsblare
- Droë mond
- Dors
- Jeuk
- Oorsuising
- Slaapprobleme
- Moeilike asemhaling
- Sooibrand
- Braking
- 'n Draaiende sensasie
- 'n Verandering in die hart se elektriese geleiding (gesien op EKG)
- 'n Hartritmeverandering (gesien op EKG)
- Inflammasie van die maagvoering (gastritis)
- Verhoogde lewerensieme (gesien op bloedtoetse)
- Veranderinge in nierfunksie (kreatinien) (gesien op bloedtoetse)
- Verhoogde bloedvetvlakke (trigliseriede) (gesien op bloedtoetse)

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem is nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte kry, praat met u dokter, apteker of verpleegster. U kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting platform (who-umc.org) wat op SAHPRA-webwerf gevind word.
Deur newe-effekte aan te meld, kan u help om meer inligting in te win oor die veiligheid van **BASMEDENE 20**.

5. Hoe om BASMEDENE 20 te bêre
Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 °C.
- Bêre in die oorspronklike verpakking/houer.
- Hou die houer in die buitenste karton.
- Beskerm teen lig/vog.
- Moet nie in 'n badkamer bêre nie.
- Moet nie gebruik na die vervaldatum wat op die etiket aangedui word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels wegdoen nie (bv. toilette).

6. Inhoud van die verpakking en ander inligting
Wat BASMEDENE 20 bevat
- Die aktiewe bestanddeel is bilastien

Die ander bestanddele is kolloïdale anhidriese silika, magnesiumstearaat, mikrokristallyne sellulose, natriumstyselglikolaat.

Hoe BASMEDENE 20 lyk en die inhoud van die pak
Wit tot naaswit, gekeepte ovaalvormige tablette gebosseleer met '2' aan die een kant van die breeklyn en '0" aan die ander kant van die breeklyn, plein aan die ander kant.
Die breeklyn is slegs bedoel om die tablet makliker te kan breek vir slukdoeleindes en nie om dit in gelyke dosisse te verdeel nie.
Gewone koudvormbare Alu-foelie – 0.025 mm Alu hardgetemperde foelie stolpverpakking. Elke stolpstrook bevat 7 of 10 tablette. Stolpstroke word in kartondose verpak.
Verpakkingsgroottes: 7, 10, 14, 20, 28, 30, 40, 50, 56 of 60 tablette. Nie alle verpakkingsgroottes word dalk bemark nie

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Hierdie pamflet was laas opgedateer in
14 Oktober 2025

Registrasienommer
56/5.7.1/0591

Toegang tot die ooreenstemmende Professionele Inligting
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Date 5 November 2025