

# SEASONZE

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S2

SEASONZE 10 mg film-coated tablets  
Cetirizine dihydrochloride  
Contains sugar (66,4 mg lactose monohydrate per tablet).

### Read all of this leaflet carefully because it contains important information for you

- SEASONZE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take SEASONZE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share SEASONZE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

### What is in this leaflet

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

#### 1. What SEASONZE is and what it is used for

SEASONZE contains the active ingredient cetirizine dihydrochloride.

SEASONZE is used to treat hayfever, rhinitis (runny nose) and urticaria (itchy rash or hives).

#### 2. What you need to know before you take SEASONZE

##### Do not take SEASONZE if:

- You are hypersensitive (allergic) to cetirizine, hydroxyzine or any of the other ingredients of SEASONZE (listed in section 6).
- You have severe kidney problems.

### Warnings and precautions

#### Take special care with SEASONZE:

- If you have problems passing urine (like spinal cord problems or prostate or bladder problems).
- If you have porphyria.
- If you have liver or kidney problems.
- It is advisable to avoid drinking alcohol with SEASONZE.
- If you are an epileptic patient or a patient at risk of seizures, as you must be closely monitored.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking SEASONZE for several days before testing, as SEASONZE may affect your allergy test results.

### Children and adolescents

SEASONZE is not recommended for use in children aged less than 6 years.

### Other medicines and SEASONZE

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

### SEASONZE with alcohol

It is recommended to avoid taking SEASONZE with alcohol.

### 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 health care provider for advice before taking SEASONZE.

You should not take SEASONZE if you are pregnant or breastfeeding your baby.

### Driving and using machines

Caution is advised when driving a vehicle or operating machinery, as drowsiness may occur often with the use of SEASONZE. You should not take more than the recommended doses as this may affect your ability to perform these tasks.

### SEASONZE contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SEASONZE.

### 3. How to take SEASONZE

Do not share medicines prescribed for you with any other person. Always take SEASONZE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

*Adults (including the elderly) and children 12 years of age or older:*  
The usual dose of SEASONZE tablets is one tablet (10 mg) daily.

*Children aged 6 to 12 years:*  
The usual dose of SEASONZE tablets is one tablet (10 mg) daily or half a tablet (5 mg) twice daily.

### If you take more SEASONZE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Symptoms of overdose include confusion, diarrhoea, dizziness, fatigue, headache, malaise (feeling unwell), mydriasis (dilating pupils), pruritis (itching), restlessness and urinary retention (difficulty in completely emptying the bladder).

### If you forget to take a dose of SEASONZE

If you miss a dose of SEASONZE, take that dose as soon as you remember. If your next dose is due within 6 hours, take this dose now and skip the next dose. Take your next dose at the normal time.  
Do not take a double dose to make up for forgotten individual doses.

### 4. Possible side effects

SEASONZE can have side effects.

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

### If any of the following happens, stop taking SEASONZE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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

### Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bleeding or bruising more easily than normal,
  - convulsions (fits),
  - recurring thoughts of harming or killing yourself,
  - changes in the way your heart beats (beating faster),
  - hepatitis (inflammation of the liver).
- These are all serious side effects. You may need urgent medical attention.

### Tell your doctor if you notice any of the following:

#### Frequent side-effects:

- sleepiness,
- dizziness,
- headache,
- pharyngitis,
- dry mouth,
- nausea (feeling sick),
- fatigue.

#### Less frequent side-effects:

- stomach pain,
- increased appetite,
- agitation, aggression, confusion, depression, sleeplessness,
- seeing or hearing things that do not exist,
- repeated and involuntary twitches, movements, or sounds (tics),
- paraesthesia (tingling or numbness of your hands and feet (pins and needles)),
- dysgeusia (altered taste), dystonia (abnormal prolonged muscular contractions), dyskinesia (involuntary movements),
- tremors (involuntary trembling or shaking of hands and feet)
- fainting,
- drowsiness,
- anxiety,
- nervousness,
- blurred vision, accommodation disorder (difficulty focusing),
- oculogyration (eyes having uncontrolled circular movements),
- diarrhoea, nausea, stomach discomfort,
- loss of bladder control or painful urination,
- lack of energy,
- feeling unwell,
- increased weight,
- abnormal liver function.

#### Side-effects with an unknown frequency:

- nightmare,
- memory loss or memory impairment,
- vertigo (sensation of spinning or swaying),
- pain in a joint,
- difficulty in emptying the bladder.

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. You can also report side effects to SAHPRA via the "Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SEASONZE.

### 5. How to store SEASONZE

- Store at or below 25 °C.
- Keep the tablets in the original packaging.
- Store all medicines out of reach of children.
- Do not use after expiry date printed on the tube or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### What SEASONZE contains

The active substance is cetirizine dihydrochloride. The other ingredients are: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry White Y-1-7000 (consisting of hypromellose, titanium dioxide, polyethylene glycol 400).

#### What SEASONZE looks like and contents of the pack

SEASONZE tablets are white to off white, round, film-coated tablets scored on the one side and plain on the other. SEASONZE tablets are available in white plastic bottles, patient ready packs or in PVC/PVDC white opaque and alu lidning blisters in cartons containing 10, 20, 28, 30, 120 or 500 tablets.

#### Holder of certificate of registration

Biotech Laboratories (Pty) Ltd  
Ground Floor, Block K West, Central Park  
400 16<sup>th</sup> Road, Randjespark, Midrand 1658  
South Africa  
Tel: 011 848 3050

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37/5.7.1/0086

# SEAZONEZE

## PASIËNTINLIGTINGSBLAD

### SKEDULERING STATUS

52

SEAZONEZE 10 mg filmbedekte tablette  
Setirisiediïdrochloried  
Bevat suiker (66,4 mg laktosemonohidraat per tablet).

### Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou

- SEAZONEZE is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy steeds SEAZONEZE versigtig neem om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie SEAZONEZE met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger

### Wat in hierdie inligtingsblad is

1. Wat SEAZONEZE is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy SEAZONEZE neem
3. Hoe om SEAZONEZE te neem
4. Moontlike nuwe-effekte
5. Hoe om SEAZONEZE te bewaar
6. Inhoud van die pakkie en ander inligting

### 1. Wat SEAZONEZE is en waarvoor dit gebruik word

SEAZONEZE bevat die aktiewe bestanddeel setirisiediïdrochloried.

SEAZONEZE word gebruik om hooikoors, rinitis (loopneus) en urtikaria (jeukerige uitslag of velbulte) te behandel.

### 2. Wat jy moet weet voordat jy SEAZONEZE neem

#### Moenie SEAZONEZE neem as:

- Jy hipersensitief (allergies) vir setirisien, hidroksien of enige van die ander bestanddele van SEAZONEZE is (gelys in afdeling 6).
- Jy ernstige nierprobleme het.

### Waarswakings en voorsorgmaatreëls

#### Wees versigtig met SEAZONEZE:

- As jy probleme het om te urineer (soos rugmurgprobleme of prostaat- of blaasprobleme).
- As jy porfirie het.
- As jy lewer- of nierprobleme het.
- Dit is raadsaam om alkohol te vermy met SEAZONEZE.
- As jy 'n epeleptiese pasiënt is of 'n pasiënt wat die risiko loop om aanvalle te kry, aangesien jy noukeurig gemonitor moet word.
- As jy geskeduleer is vir allergietoets, vra jou dokter of jy moet ophou om SEAZONEZE vir 'n paar dae voor toetsing te gebruik, aangesien SEAZONEZE jou allergietoetsresultate kan beïnvloed.

### Kinders en adolessente

SEAZONEZE word nie aanbeveel vir gebruik by kinders jonger as 6 jaar nie.

### Ander medisyne en SEAZONEZE

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

### SEAZONEZE met alkohol

Dit word aanbeveel om nie alkohol saam met SEAZONEZE te neem nie.

### Swangerskap en borsvoeding

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy SEAZONEZE neem.

Jy moet nie SEAZONEZE neem as jy swanger is of jou baba borsvoed nie.

### Bestuur en gebruik van masjiene

Dit is raadsaam om versigtig te wees wanneer jy 'n voertuig bestuur of masjinerie gebruik, aangesien lomerigheid dikwels kan voorkom met die gebruik van SEAZONEZE. Jy moet nie meer as die aanbevole dosisse neem nie, aangesien dit jou vermoë om hierdie take uit te voer kan beïnvloed.

### SEAZONEZE bevat laktosemonohidraat

As jou dokter jou ingelig het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy SEAZONEZE neem.

### 3. Hoe om SEAZONEZE te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.  
Neem altyd SEAZONEZE presies soos beskryf in hierdie pamflet of soos jou dokter of apteker vir jou gesê het. Gaan met jou dokter of apteker as jy nie seker is nie.

*Volwassenes (insluitend bejaardes) en kinders van 12 jaar of ouer:*  
Die gewone dosis SEAZONEZE tablette is een tablet (10 mg) daagliks.

*Kinders van 6 tot 12 jaar:*

Die gewone dosis SEAZONEZE tablette is een tablet (10 mg) daagliks of 'n halwe tablet (5 mg) twee keer per dag.

### As jy meer SEAZONEZE neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome van oordosis sluit in verwarrring, diarree, duiseligheid, moegheid, hoofpyn, malaise (siek voel), miëriase (verwyderde pupille), pruritis (jeuk), rusteloosheid en urinerenstese (moeilikheid om die blaas heeltemal leeg te maak).

### As jy vergeet om 'n dosis SEAZONEZE te neem

As jy 'n dosis SEAZONEZE mis, neem die dosis sodra jy onthou. As jou volgende dosis binne 6 ure geneem moet word, neem die dosis nou en slaan die volgende dosis oor. Neem jou volgende dosis op die normale tyd.  
Moenie 'n dubbeldosis neem om vergeete individuele dosisse in te haal nie.

### 4. Moontlike nuwe-effekte

SEAZONEZE kan nuwe-effekte hê.  
Nie alle nuwe-effekte wat vir SEAZONEZE aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg, of as u enige nadelige effekte ervaar terwyl u SEAZONEZE neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

### Indien enige van die volgende gebeur, hou op om SEAZONEZE te neem en vertel jou dokter dadelik of gaan na die ongevallende afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- flou word.

Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op SEAZONEZE gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

### Vertel jou dokter dadelik of gaan na die ongevallende afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- bloeding of kneusing makliker as normaal,
  - stuiptrekkings (aanvalle),
  - herhalende gedagtes om jousef seer te maak of dood te maak,
  - veranderinge in die manier waarop jou hart klop (vinniger klop),
  - hepatitis (ontsteking van die lewer).
- Dit is alles ernstige nuwe-effekte. Jy mag dalk dringende mediese hulp benodig.

### Vertel jou dokter as jy enige van die volgende opmerk:

#### Algemene nuwe-effekte:

- slaperigheid,
- duiseligheid,
- hoofpyn,
- faringitis,
- droë mond,
- naarheid (siek voel),
- moegheid.

#### Minder algemene nuwe-effekte

- maagpyn,
- verhoogde eetlus,
- agitatie, aggressie, verwarrring, depressie, slapeloosheid,
- dinge sien of hoor wat nie bestaan nie,
- herhaalde en onwillekeurige trekkings, bewegings of geluide (tics),
- parestesie (tinteling of gevoelloosheid van jou hande en voete (spelde en naalde)),
- disgeusie (veranderde smaak), distonie (abnormale langdurige spiersametrekings), dyskinesia (onwillekeurige bewegings),
- bewing (onwillekeurige bewing of bewing van hande en voete)
- floute,
- lomerigheid,
- angst,
- senuweeagtigheid,
- versterkte visie, akkommodasieversteuring (probleme om te fokus), okulogirasie (oë met onbeheerde sirkelbewegings),
- diarree, naarheid, maag ongemak,
- verlies aan blaasbeheer of pynlike urinering,
- gebrek aan energie,
- onwel gevoel,
- toename in gewig,
- abnormale lewerfunksie.

#### Nuwe-effekte met 'n onbekende voorkoms:

- nagmerrie,
  - geheueverlies of geheue inkorting,
  - vertigo (sensasie van spin of wieg),
  - pyn in 'n gewrig,
  - probleme om die blaas leeg te maak.
- Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

### Aanmelding van nuwe-effekte

As jy nuwe-effekte ervaar, praat met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die "Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van SEAZONEZE te verskaf.

### 5. Hoe om SEAZONEZE te stoor

- Bewaar teen of benede 25 °C.
- Hou die tablette in die oorspronklike verpakking.
- Berg alle medisyne buite bereik van kinders.
- Moet nie gebruik na die vervaldatum wat op die buis of karton gedruk is nie.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

### 6. Inhoud van die pakkie en ander inligting

#### Wat SEAZONEZE bevat

Die aktiewe bestanddeel is setirisiediïdrochloried.  
*Die ander bestanddele is:* kolloidale waterreyye silika, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, Opadry White Y-1-7000 (bestaan uit hipromellose, titaandioksied, polietileenlikool 400).

#### Hoe lyk SEAZONEZE en inhoud van die verpakking

SEAZONEZE tablette is wit tot naaswit, ronde, filmbedekte tablette met 'n kerf aan die een kant en glad aan die ander kant. SEAZONEZE-tablette is beskikbaar in wit plastiekbottels, pasiëntgereed-pakkies of in PVC/PVDC wit ondeursigtige en alu bedekking stulperverpakking in kartonne wat 10, 20, 28, 30, 120 of 500 tablette bevat.

#### Houer van registrasiesertifikaat

Biotech Laboratories (Edms) Bpk  
Grond Vloer, Blok K Wes, Central Park  
400 16<sup>de</sup> Weg, Randjespark, Midrand 1685  
Suid Afrika  
Tel: 011 848 3050

#### Hierdie pamflet is laas hersien:

14 Februarie 2022

#### Registrasie nommer:

37/5.7.1/0086