Front
160 mm
16 mm
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124 mm
225 mm
450 mm
28.12 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

CEZIT 5 MG
Levocetirizine dihydrochloride
Contains sugar
(lactose monohydrate 50 mg per tablet)

Read all of this leaflet carefully because it contains important information for you
CEZIT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **CEZIT** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **CEZIT** 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 after 5 days.

What is in this leaflet

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

1. What CEZIT is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of **CEZIT**.
CEZIT is an antihistamine for systemic use.
It is used for the treatment of signs of illness (symptoms) associated with:
- allergic rhinitis (including persistent allergic rhinitis);
- chronic nettle rash of unknown origin (chronic idiopathic urticaria).

2. What you need to know before you take CEZIT

Do not take CEZIT
- if you are hypersensitive (allergic) to levocetirizine dihydrochloride or any of the other ingredients of **CEZIT** (listed in section 6).
- if you or your child have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 mL/min)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions
Talk to your doctor or pharmacist before taking **CEZIT**. Take special care with **CEZIT**:
If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of **CEZIT** may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking **CEZIT** for several days before testing. This medicine may affect your allergy test results.

Children
The use of CEZIT is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

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

CEZIT with food and, drink and alcohol
Caution is advised if **CEZIT** is taken at the same time as alcohol or other medicines acting on the brain.
In sensitive patients, the concurrent administration of **CEZIT** and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.

CEZIT can be taken with or without food.

Pregnancy, breastfeeding and fertility
You should not take **CEZIT** if you are pregnant or breastfeeding your baby.
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 this medicine.

Driving and using machines
It is not always possible to predict to what extent **CEZIT** 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 **CEZIT** affects them.
Some patients being treated with **CEZIT** may experience somnolence / drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

CEZIT contains lactose monohydrate
CEZIT contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take CEZIT

Do not share medicines prescribed for you with any other person.

Always take **CEZIT** exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Adults or children aged 6 years and older:
The daily recommended dose is one tablet. The tablets should be swallowed whole with water and may be taken with or without food.

Method of administration
CEZIT tablets should be swallowed whole with water and may be taken with or without food.
You can take **CEZIT** with meals, or independently of meals. If you have a sensitive stomach, you should best take **CEZIT** after meals.

If you take more CEZIT 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 may include:
- sleepiness can occur in adults
- children may initially show a sense of excitation and restlessness followed by somnolence

If you forget to take CEZIT
Do not take a double dose to make up for forgotten individual doses, just continue taking the amounts stated in the dosage instructions.

If you stop taking CEZIT
Stopping treatment with **CEZIT** earlier than foreseen should have no detrimental effects. However, less frequently pruritus (intense itching) may occur if you stop taking **CEZIT** even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

CEZIT can have side effects.

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

If any of the following happens, stop taking/using **CEZIT** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- dry mouth
- headache
- tiredness
- somnolence / drowsiness

Less frequent side effects:
- exhaustion
- abdominal pain

Side effects with frequency unknown:
- palpitations, increased heart rate,
- fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement,
- visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements),
- painful or difficult urination, inability to completely empty the bladder, oedema,
- pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption,
- shortness of breath,
- weight increase, muscular pain, joint pain, aggressive or agitated behaviour,
- hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare,
- hepatitis, abnormal liver function,
- vomiting, increased appetite, nausea, diarrhoea
- pruritus (intense itching) upon discontinuation.

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 **"6.04 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 **CEZIT.**

5. How to store CEZIT

Store at or below 25 °C. Protect from light
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
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 CEZIT contains
- The active substance is Levocetirizine dihydrochloride 5 mg.
- The other ingredients are Contains are microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, colloidal silicon dioxide, magnesium stearate and coating agent instacoat universal white A05G10679 containing hypromellose, polyethylene glycol 400 and titanium dioxide (C.I. no. 77891).
- Contains sugar (lactose monohydrate 50 mg per tablet)

What CEZIT looks like and contents of the pack
CEZIT 5 MG:
White to off white, oval, biconvex, film-coated tablet debossed with M 17 on one side and scored on both the sides.

1) Blister Pack:
Tablets are packed in 25 µm OPA/45 µ Aluminum foil/60 µm PVC as the forming material and Plain 25 µ Aluminium foil (6-8) gsm HSL the lidding material, packed in a pre-printed carton.
Pack size include 10's and 30's tablets.
Not all packs and pack sizes are necessarily marketed.

2) HDPE Container Pack:
Tablets and silica gel sachets are packed in 30 ml & 40 ml white round HDPE container with 28 – 400 mm & 33-400 mm neck finish which are closed with 28 mm or 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton.
Pack size include 30's or 90's tablets
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
06 SEPTEMBER 2022

Registration number
CEZIT 5 MG: 52/5.7.1/0398.397

Access to the corresponding Professional Information
The corresponding professional information can be accessed at macleodssaproducts.co.za or contact 011 682 1169

Back

160 mm

4 mm

20 mm

136 mm

450 mm

28.12 mm

225 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S2

CEZIT 5 MG Tablets
Levosetirisiendihidrochloried
Bevat suiker
(laktosemonohidraat 50 mg per tablet)

Lees hierdie hele inligtingstuk noukeurig deur, want dit bevat belangrike inligting vir jou
CEZIT is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy **CEZIT** steeds versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Moet nie **CEZIT** met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advises nodig het
- Jy moet 'n dokter sien indien jou simptome vererger of nie verbeter na 5 dae nie.

Wat in hierdie inligtingstuk is

1. Wat **CEZIT** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **CEZIT** neem
3. Hoe om **CEZIT** te neem
4. Moontlike newe-effekte
5. Hoe om **CEZIT** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat CEZIT is en waarvoor dit gebruik word

Levosetrisiendihidrochloried is die akiewe bestanddeel van **CEZIT**.
CEZIT is 'n antihistamien vir sistemiese gebruik.
Dit word gebruik vir die behandeling van tekens van siektes (simptome) geassosieer met:
- allergiese rinitis (insluitend aanhoudende allergiese rinitis);
- chroniese netelroos van onbekende oorsprong (chroniese idioptiese urtikarie).

2. Wat jy behoort te weet voordat jy CEZIT neem

Moet nie CEZIT neem
- indien jy hipersensitief (allergies) vir levosetirisiendihidrochloried of enige van die ander bestanddele van **CEZIT** is nie (gelys in afdeling 6).

indien jy of jou kind 'n ernstige inkorting van nierfunksie het (erge nierversaking met kreatinien opruiming onder 10 mL/min)
- indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **CEZIT** neem. Neem spesiale sorg met **CEZIT**:
Indien jy geneig is om nie jou blaas te kan ledig nie (met toestande soos rugmurg besering or vergrote prostaat), vra asseblief jou dokter vir advies.

Indien jy ly aan epilepsie of die risiko loop om konvulsies te kry, vra asseblief jou dokter vir advies aangesien die gebruik van **CEZIT** aanvalle mag vererger.

Indien jy geskeduleer is vir allergie toetsing, vra jou dokter of jy moet ophou om **CEZIT** vir 'n paar dae voor toetsing te neem. Hierdie medisyne kan jou allergie toetsresultate beïnvloed.

Kinders
Die gebruik van **CEZIT** word nie aanbeveel in kinders jonger as 6 jaar nie, aangesien die filmbedekte tablette nie dosisaanpassing toelaat nie.

Ander medisyne en CEZIT
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

CEZIT met voedsel en vloeistof en alkohol
Omsigtigheid word aangeraai indien **CEZIT** gelyktydig geneem word saam met alkohol of ander medisyne wat op die brein inwerk.
In sensitiewe pasiënte kan die gelyktydige toediening van **CEZIT** en alkohol of ander medisyne wat op die brein inwerk bykomende vermindering in waaksaamheid en verswakking van prestasie veroorsaak.

CEZIT kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Jy moet nie **CEZIT** neem as jy swanger is of jou baba borsvoed nie.
Indien jy swanger is of borsvoed, dink dat jy dalk swanger is, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate **CEZIT** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie by bogenoemde aktiwiteite betrokke raak nie, totdat hulle bewus is van die mate waartoe **CEZIT** hulle affekteer.
Sommige pasiënte wat met **CEZIT** behandel word, kan slaperigheid/lomerigheid, moegheid en uitputting ervaar. Wees versigtig wanneer jy bestuur of masjinerie gebruik totdat jy weet hoe hierdie medisyne jou beïnvloed. Spesiale toetse het egter geen inkorting van geestelike waaksaamheid, die vermoë om te reageer of die vermoë om te bestuur in gesonde proefpersone getoon nadat hulle levosetirisien in die aanbevole dosis geneem het nie.

CEZIT bevat laktosemonohidraat
CEZIT bevat 'n suiker naamlik laktose. Indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne gebruik.

3. Hoe om CEZIT te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **CEZIT** presies soos jou dokter of apteker vir jou gesê het. Vra vir jou dokter of apteker indien jy onseker is.

Volwassenes of kinders van 6 jaar en ouer:
Die daaglikse aanbevole dosis is een tablet. Die tablette moet heel, met water, ingesluk word en kan met of sonder kos geneem word.

Metode van toediening
CEZIT tablette moet heel met water ingesluk word en kan met of sonder kos geneem word.
Jy kan **CEZIT** saam met etes neem, of onafhanklik van etes. As jy 'n sensitiewe maag het, moet jy eerder **CEZIT** na etes neem.

Indien jy meer CEZIT neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Simptome van oordosering kan die volgende insluit:
- slaperigheid kan by volwassenes voorkom
- kinders kan aanvanklik 'n gevoel van opgewondenheid en rusteloosheid toon, gevolg deur slaperigheid

Indien jy vergeet om CEZIT te neem
Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie, gaan net voort om die hoeveelhede genoem in die dosis instruksies, te neem.

Indien jy ophou om CEZIT te neem
Die staak van behandeling met **CEZIT**, vroeër as wat voorsien is, behoort geen nadelige uitwerking te hê nie. Pruritis (intense jeuk) kan egter soms voorkom indien jy ophou om **CEZIT** te neem, selfs al was daardie simptome nie teenwoordig voor die aanvang van behandeling nie. Die simptome kan spontaan verdwyn. In sommige gevalle kan die simptome intens wees en dit kan vereis dat behandeling weer begin word. Die simptome behoort te verdwyn wanneer die behandeling weer begin word.

Indien jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. Moontlike newe-effekte

CEZIT kan newe-effekte hê.

Nie al die newe-effekte wat vir **CEZIT** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **CEZIT** neem, kontak jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **CEZIT** te neem/gebruik en sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal
- uitslag of gejeuk
- floute

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **CEZIT** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.
Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte:
- droë mond
- hoofpyn
- moegheid
- slaperigheid/lomerigheid

Minder gereelde newe-effekte
- uitputting
- abdominale pyn

Newe-effekte met onbekende frekwensie:
- hartkloppings, verhoogde harttempo,
- aanvalle, spelde en naalde, duiseligheid, floute, bewing, disgeusie (verwringing van die smaaksintuig), sensasie van draaiing of beweging,
- visuele versteurings, dowwe visie, okulogirasie (oë met onbeheerde sirkelbewegings),
- pynlike of moeilike urinering, onvermoë om die blaas heeltemal leeg te maak, edeem,
- pruritus (jeuk), uitslag, urtikarie (swelling, rooiheid en jeuk van die vel), veluitslag,
- kort van asem,
- toename in gewig, spierpyn, gewrigspyn, aggressiewe of opgewekte gedrag,
- hallusinasie, depressie, slapeloosheid, herhalende gedagtes van, of beheptheid met selfmoord, nagmerrie,
- hepatitis, abnormale lewerfunksie,
- braking, verhoogde eetlus, naarheid, diaree
- pruritus (intense jeuk) by staking.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra .org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **CEZIT**.

5. Hoe om CEZIT te bewaar

Bewaar by of benede 25°C. Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houer dig toe.
Stoor in die oorspronklike houer om sodoende teen lig en vog te beskerm.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat op die stulpstrook/etiket/ karton/bottel aangebring is, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat CEZIT bevat
- Die aktiewe bestanddeel is Levosetirisiendihidrochloried 5 mg.
- Die ander bestanddele is mikrokristallyne sellulose, natriumkruiskarmellose, laktosemonohidraat, kolloïdale silikondioksied, magnesiumstearaat en bedekkingsmiddel instacoat universele wit A05G10679 wat hipromellose, poliëtileenglikol 400 en titaandioksied (C.I. no. 77891) bevat.
- Bevat suiker (laktosemonohidraat 50 mg per tablet)

Hoe CEZIT lyk en inhoud van die pak
CEZIT 5 MG:
Wit tot naaswit, ovaal, bikonveks, filmbedekte tablet met M 17 aan die een kant gegraveer en aan albei kante gekerf.
1) Stulpstrook verpakking:
Tablette word verpak in 25 µm OPA/45 µ Aluminiumfoelie/60 µm PVC as die vormingsmateriaal en Gewone 25 µ Aluminiumfoelie (6-8) gsm HSL die dekmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgrootte sluit 10 of 30's tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

2) HDPE houer verpakking:
Tablette en sakkies met silikagel bevat word verpak in 30 ml & 40 ml wit ronde HDPE houer met 28 – 400 mm & 33-400 mm nekafwerking wat toegemaak is met 28 mm of 33 mm kinderbestande sluiting met pulp en hitteseëlvoering en in buitenste karton verpak.
Verpakkingsgrootte sluit 30's of 90's tablette in
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk was hersien in
06 SEPTEMBER 2022

PM04091002

Registrasienommer
CEZIT 5 MG: 52/5.7.1/0398.397

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan by macleodssaproducts.co.za verkry word of deur 011 682 1169 te kontak

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Professional information removed

1. Product: CEZIT 5 MG (Levocetirizine dihydrochloride tablets 5 mg)						
2. Country: South Africa - Pharmafen			**3. Packaging component: Patient Information Leaflet**			
4. No. of Colours: 1 Colour			**5. Pantone Shade No.: Black**			
6. Specification: 50 GSM Maplitho Paper						
7. Machine Layout No.: NA			**8. Dimensions: 450 (L) x 160 (W) mm**			
9. Design / Style: Front - Back			**10. Item code No.: PM04091002**			
11. Artwork has been made: Actual Size			**12. Pharma code No.: Front - 32815 mini , Back - 32816 mini**			
13. Barcode/NDC no: NA			**14. Supersedes Item code No: PM04091001**			
15. Revision no: 01			**A/W File name:X:\Levocetirizine\Pharmafen\02\Levocetirizine 5 mg PIL - PM04091002.cdr**			
Approved By:			**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**MEDICAL/RAD**	**QC**	**PRODN**	**QA**	**PHARMAFEN**

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa - Pharmafen	**PM04091001**	**28/03/2023**	**Not Implement**
2) Professional information removed	**PM04091002**		