PATIENT INFORMATION LEAFLET

RupAllerg10

Rupatadine (as Fumarate) 10 mg

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

RUPALLERG 10, tablets contain 10 mg rupatadine per tablet.

Read all of this leaflet carefully before you start taking **RUPALLERG 10**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **RUPALLERG 10** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT RUPALLERG 10 CONTAINS

- The active ingredient is rupatadine fumarate 12,80 mg equivalent to rupatadine 10 mg base.
- The other ingredients are: Cellulose-microcrystalline, lactose monohydrate, magnesium stearate, pregelatinised maize starch, red iron oxide (E-172) and yellow iron oxide (E-172).
- EACH TABLET CONTAINS LACTOSE, A SUGAR.

WHAT RUPALLERG 10 IS USED FOR

RUPALLERG 10 relieves symptoms of allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose.
RUPALLERG 10 is also used to relieve symptoms associated with urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling.)

BEFORE YOU TAKE RUPALLERG 10

Do not take RUPALLERG 10:

- If you are hypersensitive (allergic) to rupatadine or any of the other ingredients of **RUPALLERG 10**.
- **RUPALLERG 10** is not recommended for use in children below 12 years of age.
- If you are pregnant or breastfeeding.

Take special care with RUPALLERG 10:

- If you have, or have had liver or kidney disease, ask your doctor for advice. The use of **RUPALLERG 10** is not recommended in patients with impaired kidney or liver functions.
- **RUPALLERG 10** contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking it.
- **RUPALLERG 10**
  - should be used with caution in patients with known prolongation or a longer period of the QT interval which means the time between the Q wave and the end of the T wave in the heart's electrical cycle,
  - patients with uncorrected low potassium,
  - patients with ongoing prodysrhythmic conditions which means it is a medicine caused or medicine aggravated heart rhythm condition, such as clinically significant slow heart rate,
  - and acute decreased blood flow to your heart,
  - If you are older than 65, ask your doctor or pharmacist.

Taking RUPALLERG 10 with food and drink:

- Can be taken with or without food.
- It is recommended to avoid intake of grapefruit juice along with **RUPALLERG 10**.
- It is not advisable to use alcohol concomitant with **RUPALLERG 10**.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.
The use of **RUPALLERG 10** is contraindicated during pregnancy.
As rupatadine is excreted in animal milk and due to potential harmful effects in neonates, the use of **RUPALLERG 10** should be avoided during breastfeeding.

Driving and using machinery

At recommended doses, **RUPALLERG 10** is not expected to influence your ability to drive or use machinery. However, when you first start taking **RUPALLERG 10** you should take care to see how the treatment affects you before driving or using machinery.

Important information about some of the ingredients of RUPALLERG 10:

- **RUPALLERG 10** contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking it.

Taking other medicines with RUPALLERG 10:

Always tell your health care professional if you are taking any other medicine, this includes complementary or traditional medicines.

- If you are taking **RUPALLERG 10** do not take medicines containing ketoconazole or erythromycin.
- **RUPALLERG 10** should be used with caution when you are on statin containing medicine for high cholesterol.

HOW TO TAKE RUPALLERG 10

Do not share medicines prescribed for you with any other person.
Always take **RUPALLERG 10** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The recommended dose for adults and adolescents (over 12 years of age) is 10 mg (one tablet) once a day with or without food.
Your doctor will tell you how long your treatment with **RUPALLERG 10** will last.
If you have the impression that the effect of **RUPALLERG 10** is too strong or too weak, tell your doctor or pharmacist.
Swallow **RUPALLERG 10** with a glass of water.

If you take more RUPALLERG 10 than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take RUPALLERG 10:

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with RUPALLERG 10 is stopped:

Your symptoms of your allergy may become worse or return if you stop your treatment.

POSSIBLE SIDE EFFECTS

RUPALLERG 10 can have side effects.
Not all side effects reported for **RUPALLERG 10** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking* RUPALLERG 10 *and tell your doctor immediately or go to the casualty department at your nearest hospital:

Less frequent - Nose bleeding, rash, muscle pain.

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

Less frequent - Back pain, stiffness in the joints, fatigue, and lack of energy.

Tell your doctor if you notice any of the following:

Less frequent - Nasal dryness, upper respiratory disorders, disturbance in attention, nausea, upper abdominal pain, diarrhoea, dyspepsia, vomiting, abdominal pain, constipation, thirst, malaise and pyrexia.
Frequent - dry mouth, feeling tired, somnolence, headache and dizziness.

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

STORING AND DISPOSING OF RUPALLERG 10

Store at or below 30 ºC. Keep the blisters in the outer carton until required for use. Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

PRESENTATION OF RUPALLERG 10

RUPALLERG 10 tablets are packed in the following:
PVC-PVDC foil and aluminium blister packaging with 10 tablets each.
In a pack size of 10 or 30 (1 or 3 strips of 10 tablets in a cardboard carton).

IDENTIFICATION OF RUPALLERG 10

RUPALLERG 10 tablets are round, biconvex, light salmon pink in colour with no markings.

REGISTRATION NUMBER/REFERENCE NUMBER

51/5.7.1/0694

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

iNova Pharmaceuticals (Pty) Ltd
15e Riley Road, Bedfordview, South Africa
Marketed by: Acino Pharma (Pty) Ltd

DATE OF PUBLICATION

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ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION FOR HEALTHCARE PROFESSIONALS

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.

A5432

rupallerg pil_21.indd 1 **Product name:** rupallerg 10 • **Date:** 19/4/2021 • **Created by:** Linda_Duigan_Z4 • **Component:** PIL • **UIC:** A5432 • **Colours:** black only • **Specs:** 150.0 LPI • 2021/04/19 12:58

PASIËNTINLIGTINGSPAMFLET

RupAllerg10

Rupatadien (as Fumaraat) 10 mg

SKEDULERINGSTATUS

S2

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

RUPALLERG 10 tablette bevat 10 mg rupatadien per tablet.

Lees hierdie hele pamflet sorgvuldig deur voordat jy **RUPALLERG 10** begin neem

- Hou hierdie pamflet, jy sal dit miskien later weer moet lees.
- As jy verdere vrae het, vra gerus jou dokter of apteker.
- **RUPALLERG 10** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag hulle kwaad doen, selfs al is hul simptome diesefde as joune.

WAT RUPALLERG 10 BEVAT

- Die aktiewe bestanddeel is rupatadienfumaraat 12,80 mg gelykstaande aan rupatadien 10 mg basis.
- Die ander bestanddele is: Sellulosemikrokristallyn, laktosemonohidraat, magnesiumstearaat, pregegelatiniseerde mieliestysel, rooi ysteroksied (E-172) en geel ysteroksied (E-172).
- BEVAT SUIKER: laktosemonohidraat 61,1 mg.

WAARVOOR RUPALLERG 10 GEBRUIK WORD

RUPALLERG 10 verlig simptome van allergiese rinitis soos nies, 'n loopneus, jeuk in die oë en neus.

RUPALLERG 10 word ook gebruik om simptome geassosieer met urtikaria ('n allergiese veluitslag), soos jeuk en netelroos (gelokaliseerde velrooiheid en swelsel), te verlig.

VOORDAT JY RUPALLERG 10 NEEM

Moenie RUPALLERG 10 neem indien:

- Jy hipersensitief (allergies) vir rupatadien of enige van die ander bestanddele van **RUPALLERG 10** is nie.
- **RUPALLERG 10** word nie aanbeveel vir gebruik in kinders jonger as 12 jaar nie.
- Jy swanger is of borsvoed nie.

Wees veral versigtig met RUPALLERG 10

- As jy lewer- of niersiekte het of gehad het, raadpleeg eers jou dokter. Die gebruik van **RUPALLERG 10** deur pasiënte met verswakte nier- of lewerfunksie word nie aanbeveel nie.
- **RUPALLERG 10** bevat laktose. As jou dokter vir jou gesê het dat jy onverdraagsaam vir sekere suikers is, raadpleeg jou dokter voordat jy dit neem.
- **RUPALLERG 10**
  - o moet versigtig gebruik word in pasiënte met bekende verlenging van, of 'n langer periode van die QT-interval, wat die tyd tussen die Q-golf en die einde van die T-golf in die hart se elektriese sikus beteken,
  - o pasiënte met lae kaliumvlakke wat nie reggestel is nie,
  - o pasiënte met 'n voortdurende prodisritmiese toestand, wat 'n hartritmeaandoening is wat deur medisyne veroorsaak of vererger word, soos 'n klinies betekenisvolle stadige harttempo,
  - o en akuut verlaagde bloedvloei na jou hart.
  - o As jy ouer as 65 is, vra eers jou dokter of apteker.

Neem van RUPALLERG 10 saam met voedsel en drank:

- o Kan met of sonder voedsel geneem word.
- o Daar word aanbeveel dat jy nie **RUPALLERG 10** tesame met pomelosap neem nie.
- o Dit is nie raadsaam om alkohol saam met **RUPALLERG 10** te gebruik nie.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige voordat jy hierdie middel neem.
Die gebruik van **RUPALLERG 10** tydens swangerskap word teenaangedui.
Aangesien rupatadien in dieremelk uitgeskei word en vanweë potensiële skadelike uitwerkings op pasgebore babas, moet die gebruik van **RUPALLERG 10** tydens borsvoeding vermy word.

Bestuur en gebruik van masjinerie

Teen aanbevole dosisse word daar nie verwag dat **RUPALLERG 10** jou vermoë om te bestuur of masjinerie te gebruik sal beïnvloed nie. Wanneer jy egter **RUPALLERG 10** die eerste keer begin gebruik, lê omsigtigheid aan die dag om te sien hoe die behandeling jou affekteer voordat jy bestuur of masjinerie gebruik.

Belangrike inligting oor sommige van die bestanddele van RUPALLERG 10:

- **RUPALLERG 10** bevat laktose. As jou dokter vir jou gesê het dat jy onverdraagsaam vir sommige suikers is, kontak jou dokter voordat jy dit neem.

Die neem van ander medisyne saam met RUPALLERG 10:

Sê altyd vir jou gesondheidskundige as jy ander medisyne neem, insluitend aanvullende of tradisionele middels.

- o As jy **RUPALLERG 10** neem, moenie middels neem wat ketokonasool of eritromisien bevat nie.
- o **RUPALLERG 10** moet versigtig gebruik word wanneer jy statien bevattende middels vir hoë cholesterol neem.

HOE OM RUPALLERG 10 TE NEEM

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem **RUPALLERG 10** altyd presies soos jou dokter vir jou gesê het. Jy behoort by jou dokter of apteker seker te maak as jy twyfel.
Die aanbevole dosis vir volwassenes en jeugdiges (ouer as 12 jaar) is 10 mg (een tablet) een maal per dag met of sonder voedsel.
Jou dokter sal vir jou sê hoe lank jou behandeling met **RUPALLERG 10** sal duur.
As jy die indruk kry dat die effek van **RUPALLERG 10** te sterk of te swak is, sê vir jou dokter of apteker.
Sluk **RUPALLERG 10** met 'n glas water.

As jy meer RUPALLERG 10 neem as wat jy veronderstel was:

In die geval van oordosering, kontak jou dokter of apteker. As hulle nie beskikbaar is nie, kry hulp by jou naaste hospitaal of gifbeheersentrum.

As jy vergeet om RUPALLERG 10 te neem:

Moenie 'n dubbeldosis neem om op te maak vir individuele dosisse wat vergeet is nie.

Effek wanneer behandeling met RUPALLERG 10 gestaak word:

Jou simptome van jou allergie kan erger word of terugkeer as jy jou behandeling staak.

MOONTLIKE NEWE-EFFEKTE

RUPALLERG 10 kan newe-effekte hê.
Nie alle newe-effekte wat vir **RUPALLERG 10** vermeld is, is by hierdie pamflet ingesluit nie. As jou algemene gesondheid erger word of as jy enige ongunstige effek ervaar terwyl jy hierdie middel neem, raadpleeg asseblief jou dokter, apteker of gesondheidskundige.

As enige van die volgende gebeur, hou op om* RUPALLERG 10 *te neem en kontak dadelik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

Minder dikwels – Neusbloeding, uitslag, spierpyn.

Kontak dadelik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende ervaar:

Minder dikwels – Rugpyn, styfheid in die gewrigte, uitputting, en gebrek aan energie.

Kontak jou dokter as jy enige van die volgende ervaar:

Minder dikwels – Droë neus, aandoenings van die boonste lugweë, aandagversteuring, naarheid, boonste abdominale pyn, diarree, slegte spysvertering, braking, maagpyn, hardlywigheid, dors, algemene ongesteldheid, koors.
Dikwels – droë mond, moegheid, slaperigheid, hoofpyn, duiseligheid.

As jy enige newe-effekte bemerk wat nie in hierdie pamflet genoem word nie, sê asseblief vir jou dokter of apteker.

BEWARING EN WEGGOOI VAN RUPALLERG 10

Bewaar teen of benede 30 ºC. Hou die stolpverpakkings in die karton totdat benodig vir gebruik. Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS

AANBIEDING VAN RUPALLERG 10

RUPALLERG 10 tablette word in die volgende verpak:
PVC-PVDC foelie en aluminium stolpverpakking van 10 tablette elk.
In verpakkings van 10 of 30 (1 of 3 stroke van 10 tablette in 'n kartonhouer).

IDENTIFIKASIE VAN RUPALLERG 10

RUPALLERG 10 tablette is rond, bikonveks, het 'n ligte salmpienk kleur, met geen merktekens nie.

REGISTRASIENOMMER/VERWYSINGSNOMMER

51/5.7.1/0694

NAAM EN BESIGHEIDSADRES VAN REGISTRASIEHOUER

iNova Pharmaceuticals (Edms) Bpk
Riley Weg 15e, Bedfordview, Suid-Afrika
Bemark deur: Acino Pharma (Edms) Bpk

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TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING VIR GESONDHEIDSPRAKTISYNS

Volledige professionele inligting kan by www.inovapharma.co.za gekry word of op versoek van iNova Pharmaceuticals.