CADILA PHARMACEUTICALS LIMITED

ANNEXURE - I
ART WORK APPROVAL FORM

(Ref. SOP. No.: DFD080)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

RUALIDINE 10 tablet
Rupatadine fumarate
Contains sugar: lactose monohydrate 60,00 mg per tablet.

Read all of this leaflet carefully because it contains important information for you
RUALIDINE 10 is available without a doctor's prescription. Nevertheless, you still need to use RUALIDINE 10 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RUALIDINE 10 with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What RUALIDINE 10 is and what it is used for
2. What you need to know before you take RUALIDINE 10
3. How to take RUALIDINE 10
4. Possible side effects
5. How to store RUALIDINE 10
6. Contents of the pack and other information

1. What RUALIDINE 10 is and what it is used for
RUALIDINE 10 is a long-acting, non-sedating antihistamine. RUALIDINE 10 is indicated in adults and adolescents (over 12 years of age).
RUALIDINE 10 relieves the symptoms of allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose. RUALIDINE 10 is also used to relieve the symptoms associated with urticaria (an allergic skin rash) such as itching and hives (localised skin redness and swelling).

2. What you need to know before you take RUALIDINE 10
Do not take RUALIDINE 10:
- If you are hypersensitive (allergic) to rupatadine or any of the other ingredients of this medicine (listed in section 6);
- If you are below the age of 12;
- If you are pregnant or suspect that you are pregnant or breastfeeding.

Warnings and precautions
Take special care with RUALIDINE 10
- If you suffer from kidney or liver problems, ask your doctor for advice as RUALIDINE 10 is, at present, not recommended in patients with impaired kidney or liver functions.
- RUALIDINE 10 should be used with caution in patients with low blood levels of potassium and/or certain abnormal pattern of heartbeat (known prolongation of the QT interval on ECG) which can occur in some forms of heart disease.
- If you are older than 65, ask your doctor or your pharmacist.

Children
RUALIDINE 10 is not recommended for use in children under 12 years as safety is not established.

Other medicines and RUALIDINE 10
Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your healthcare professional if you are currently taking any of the following:
- Medicines used to treat infections, e.g., itraconazole, ketoconazole, voriconazole, posaconazole, erythromycin, fluconazole, clarithromycin.
- Nefazodone and fluoxetine (medicines used to treat depression).
- Medicines used to treat HIV (protease inhibitors).
- Diltiazem (medicine used to treat certain heart conditions).
- CNS depressants (medicines used to treat anxiety, panic attacks and acute stress reactions and sleep disorders).
- Statins (medicines to help lower cholesterol levels in the blood).
- Alcohol, as rupatadine may increase the impairment caused by alcohol intake.

RUALIDINE 10 with food, drink and/or alcohol
- Do not take RUALIDINE 10 with grapefruit juice.
- RUALIDINE 10 should be used with caution when administered with alcohol.

Pregnancy and breastfeeding
Do not take RUALIDINE 10 when you are pregnant or 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 RUALIDINE 10.

Driving and using machines
It is not always possible to predict to what extent RUALIDINE 10 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 RUALIDINE 10 affects them. However, at the recommended dosage, RUALIDINE 10 is not expected to influence the ability to drive or use machinery.

RUALIDINE 10 contains 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 RUALIDINE 10
Do not share medicines prescribed for you with any other person.
Always take RUALIDINE 10 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.
RUALIDINE 10 is for adolescents (from 12 years and older) and adults.
The usual dose is one tablet (10 mg) per day.
Take the tablet at the same time of day, with a glass of water.
RUALIDINE 10 can be taken with or without meals.
Children
RUALIDINE 10 is not recommended in children under the age of 12 years.

If you take more RUALIDINE 10 than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Overdose may cause drowsiness.
Should overdose on RUALIDINE 10 occur, treatment will be symptomatic and supportive.

If you forget to take RUALIDINE 10
Do not take a double dose to make up for forgotten individual doses.
If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you normally would. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects
RUALIDINE 10 can have side effects.
Not all side effects reported for RUALIDINE 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RUALIDINE 10, please inform your healthcare provider for advice.

If any of the following happens, stop taking RUALIDINE 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of hands, feet, ankles, face, lips and mouth, tongue 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 reaction to RUALIDINE 10. 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:
- Chest pain,
- Angina,
- Changes in the way your heart beats, for example, if you notice it beating faster,
- Difficulty breathing,
- Signs of recurrent infections, such as fever or sore throat,
- Less urine than is normal to you,
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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:
- Dizziness, headache, somnolence,
- Dry mouth,
- Sensation of weakness and fatigue.

Less frequent side effects:
- Sore throat, running nose,
- Increased appetite,
- Irritability,
- Difficulty concentrating,
- Cough, dry throat, nosebleeds, nasal dryness, pain in tonsils area (oropharyngeal pain),
- Stomach pain, diarrhoea, indigestion, nausea, vomiting, constipation,
- Rash,
- Back pain, joint pain, muscle pain,
- General discomfort, fever, thirst,
- Changes in some laboratory blood tests,
- Increase in weight.

Side effects with unknown frequency:
- Allergic reactions (including anaphylactic reactions, angioedema, urticaria, genital erythema, erythema, conjunctival hyperaemia, blepharitis, and blisters),
- Disorientation,
- Unable to walk in the normal way (abnormal gait),
- Increased sweating,
- Tremor,
- Rapid or irregular heartbeat (tachycardia and palpitations).

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 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 RUALIDINE 10.

5. How to store RUALIDINE 10
Store all medicines out of reach of children.
Store at or below 30 °C.
Store the tablet in the original packaging until required for use.
Do not use after the expiry date printed on the carton and blister.
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 RUALIDINE 10 contains
- The active ingredient is rupatadine fumarate.
- The other ingredients are Iron oxide red (77491), iron oxide yellow (77492), lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch.

What RUALIDINE 10 looks like
RUALIDINE 10 is salmon coloured, 6,35 mm ± 0,1 mm round, biconvex, uncoated tablets, plain on both sides.
RUALIDINE 10 is packed in blister packs consisting of white colour PVC/PVDC foil as the forming material and pre-printed aluminium foil as the lidding material. Each blister contains 10 tablets. The blisters are packed in cartons.
Pack sizes: 10, 20, 30 tablets.
Not all pack sizes will be marketed.

Holder of Certificate of Registration
Strides Pharma (SA) (Pty) Ltd.
3 Gwen Lane, 4th Floor,
Sandton, 2031.
Email: pv@trinitypharma.co.za
Contact number: +27 (0)10 594 5610

This leaflet was last revised in
04 February 2025

Registration number
57/5.7.1/0028

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

BS-07/04/25-V01

CADILA PHARMACEUTICALS LTD.

Product Rualadine 10 mg **Market** Export (Strides Pharma-SA) **Dimension** 240 x 240 mm
Item code OSET0218 **Mfg. Location** Dholka **Component** Leaflet - Front Side **Change part Layout:** NA
Substrate: 40 gsm Bilble Paper Pack Insert (Folding size : 120 x 30)
Superseded item code No. : NA **Color :** P Black C **No. of. Colors :** 01 **Pharma Code :** 5974
Version : 00 **Reason for issue :** New Artwork

Claudia Law - Approved - 08.04.2025

CADILA PHARMACEUTICALS LIMITED

ANNEXURE - I
ART WORK APPROVAL FORM

(Ref. SOP. No.: DFD080)

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S2

RUALIDINE 10 tablet
Rupatadienfumaraat
Bevat suiker: laktosemonohidraat 60,00 mg per tablet.

Lees hierdie hele pamflet deeglik deur, aangesien dit belangrike inligting vir u bevat
RUALIDINE 10 is sonder 'n doktersvoorskrif beskikbaar. U sal nogtans RUALIDINE 10 met sorg moet gebruik om die beste resultate daarmee te behaal.
- Hou hierdie pamflet. U sal dit miskien later weer moet lees.
- Moet nie RUALIDINE 10 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 RUALIDINE 10 is en waarvoor dit gebruik word
2. Wat u moet weet voordat u RUALIDINE 10 neem
3. Hoe om RUALIDINE 10 te neem
4. Moontlike newe-effekte
5. Hoe om RUALIDINE 10 te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat RUALIDINE 10 is en waarvoor dit gebruik word
RUALIDINE 10 is 'n langwerkende, nie-sederende antihistamien. RUALIDINE 10 word aangedui vir volwassenes en adolessente (ouer as 12 jaar).
RUALIDINE 10 verlig die simptome van allergiese rinitis soos nies, loopneus, jeuk in die oë en neus.
RUALIDINE 10 word ook gebruik om die simptome geassosieer met urtikaria ('n allergiese veluitslag), soos jeuk en netelroos (gelokaliseerde velrooiheid en swelling) te verlig.

2. Wat u moet weet voordat u RUALIDINE 10 neem
Moet nie RUALIDINE 10 neem:
- Indien u hipersensitief (allergies) is vir rupatadien of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6);
- Indien u onder die ouderdom van 12 is;
- Indien u swanger is of vermoed dat u swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met RUALIDINE 10
- Indien u aan nier- of lewerprobleme ly, vra u dokter vir advies aangesien RUALIDINE 10 nie tans aanbeveel word by pasiënte met verswakte nier- of lewerfunksie nie.
- RUALIDINE 10 moet versigtig gebruik word by pasiënte met lae kaliumbloedvlakke en/of sekere abnormale hartkloppatroon (bekende verlenging van die QT-interval op EKG) wat in sommige vorme van hartsiektes kan voorkom.
- Indien u ouer as 65 is, vra eers u dokter of apteker.

Kinders
RUALIDINE 10 word nie aanbeveel vir gebruik by kinders onder 12 jaar nie, aangesien die veiligheid nie vasgestel is nie.

Ander medisyne en RUALIDINE 10
Noem altyd aan u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit komplimentêre of tradisionele medisyne in).
Stel asseblief u gesondheidsorgdeskundige in kennis indien u tans enige van die volgende gebruik:
- Medisyne wat gebruik word om infeksies te behandel, bv. itrakonasool, ketokonasool, vorikonasool, posakonasool, eritromisien, flukonasool, klaritromisien.
- Nefasodoon en fluoksetien (medisyne wat gebruik word om depressie te behandel).
- Medisyne wat gebruik word om MIV te behandel (protease-inhibeerders).
- Diltiasiem (medisyne wat gebruik word om sekere harttoestande te behandel).
- SSS-depressante (medisyne wat gebruik word om angs, paniekaanvalle en akute stresreaksies en slaapversteurings te behandel).
- Statiene (medisyne wat help om cholesterolvlakke in die bloed te verlaag).
- Alkohol, aangesien rupatadien die inkorting wat deur alkoholinname veroorsaak word, kan verhoog.

RUALIDINE 10 met voedsel, drank en/of alkohol
- Moet nie RUALIDINE 10 saam met pomelosap neem nie.
- RUALIDINE 10 moet met omsigtigheid gebruik word wanneer dit saam met alkohol toegedien word.

Swangerskap en borsvoeding
Moet nie RUALIDINE 10 neem wanneer u swanger is of borsvoed nie.
Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u RUALIDINE 10 neem.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot watter mate RUALIDINE 10 met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet toesien dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waarin RUALIDINE 10 hulle affekteer nie. By die aanbevole dosis word daar egter nie van RUALIDINE 10 verwag om die vermoë om te bestuur of masjinerie te gebruik, te beïnvloed nie.

RUALIDINE 10 bevat laktose
Indien u dokter aan u gesê het dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u hierdie medisyne gebruik.

3. Hoe om RUALIDINE 10 te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem RUALIDINE 10 altyd presies soos in hierdie pamflet beskryf word of soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.
RUALIDINE 10 is vir adolessente (vanaf 12 jaar en ouer) en volwassenes.
Die gewone dosis is een tablet (10 mg) per dag.
Neem die tablet op dieselfde tyd van die dag, met 'n glas water.
RUALIDINE 10 kan met of sonder voedsel geneem word.
Kinders
RUALIDINE 10 word nie aanbeveel by kinders onder die ouderdom van 12 jaar nie.

Indien u meer RUALIDINE 10 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.
Oordosering kan lomerigheid veroorsaak.
Indien oordosering met RUALIDINE 10 voorkom, sal die behandeling simptomaties en ondersteunend wees.

Indien u vergeet om RUALIDINE 10 te neem
Moet nie 'n dubbele dosis neem om die vergete individuele dosisse op te maak nie.
Indien dit amper tyd is vir u volgende dosis, slaan die gemiste dosis oor en neem die volgende dosis wanneer u veronderstel is om dit te neem. Andersins, neem dit sodra u onthou, en gaan dan terug na die neem van u tablette soos u normaalweg sou doen. Indien u nie seker is of u die dosis moet oorslaan nie, praat met u dokter of apteker.

4. Moontlike newe-effekte
RUALIDINE 10 kan newe-effekte hê.
Nie alle newe-effekte wat vir RUALIDINE 10 gerapporteer is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of indien u onaangename effekte ervaar tydens die gebruik van RUALIDINE 10, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, stop om RUALIDINE 10 te neem en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van hande, voete, enkels, gesig, lippe en mond, tong of keel wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien u dit ondervind, het u moontlik 'n ernstige reaksie teen RUALIDINE 10 gehad. U mag dalk dringende mediese hulp of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- Borspyn,
- Angina,
- Veranderinge in die manier waarop u hart klop, byvoorbeeld, as u agterkom dat dit vinniger klop,
- Moeilike asemhaling,
- Tekens van herhalende infeksies soos koors of seer keel,
- Minder urine as wat normaal is vir u,
- Vergeling van die vel en oë, donker urine en moegheid wat simptome van lewerprobleme kan wees.

Hierdie is almal ernstige newe-effekte. U mag dalk dringende mediese hulp benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- Duiseligheid, hoofpyn, slaperigheid,
- Droë mond,
- Gevoel van swakheid en moegheid.

Minder gereelde newe-effekte:
- Seer keel, loopneus.
- Verhoogde eetlus,
- Prikkelbaarheid,
- Aandagversteuring,
- Hoes, droë keel, neusbloeding, nasale droogheid, pyn in mangelarea (orofaringeale pyn),
- Maagpyn, diarree, slegte spysvertering, naarheid, braking, hardlywigheid,
- Uitslag,
- Rugpyn, gewrigspyn, spierpyn,
- Algemene ongemak, koors, dors,
- Veranderinge in sommige laboratorium bloedtoetse,
- Toename in gewig.

Newe-effekte met onbekende frekwensie:
- Allergiese reaksies (insluitend anafilaktiese reaksies, angioedeem urtikaria, genitale eriteem, eriteem, konjunktivale hiperemie, blefaritis en blase),
- Disoriëntasie,
- Onvermoë om normaal te loop (abnormale gang),
- Verhoogde sweet,
- Bewing,
- Vinnige of onreëlmatige hartklop (tagikardie en hartkloppings).

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 ervaar, praat met u dokter of apteker. U kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) gevind op SAHPRA se webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting in te win oor die veiligheid van RUALIDINE 10.

5. Hoe om RUALIDINE 10 te bêre
Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 30 °C.
Bêre die tablet in die oorspronklike verpakking totdat dit benodig word vir gebruik.
Moet nie gebruik na die vervaldatum wat op die karton en stulpverpakking gedruk is 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 RUALIDINE 10 bevat
- Die aktiewe bestanddeel is rupatadienfumaraat.
- Die ander bestanddele is ysteroksiedrooi (77491), ysteroksiedgeel (77492), laktosemonohidraat, magnesiumstearaat, mikrokristallien sellulose en voorafgegelatineerde stysel.

Hoe RUALIDINE 10 lyk
RUALIDINE 10 is salmkleurige, 6,35 mm ± 0,1 mm ronde, bikonvekse, onbedekte tablette, plein aan beide kante.
RUALIDINE 10 word in stulpverpakkings verpak wat bestaan uit wit kleurige PVC/PVDC foelie as die vormingsmateriaal en voorafgedrukte aluminiumfoelie as die bedekkingsmateriaal. Elke stulpverpakking bevat 10 tablette. Die stulpverpakkings word in kartonne verpak.
Verpakkingsgroottes: 10, 20, 30 tablette.
Nie alle verpakkingsgroottes sal bemark word nie.

Houer van Registrasiesertifikaat
Strides Pharma (SA) (Edms.) Bpk.
3 Gwen Laan, 4de Vloer,
Sandton, 2031.
E-pos: pv@trinitypharma.co.za
Kontaknommer: +27 (0)10 594 5610

Hierdie pamflet was laas opgedateer in
04 Februarie 2025

Registrasienommer
57/5.7.1/0028

Toegang tot die ooreenstemmende Professionele Inligting
www.trinitypharma.co.za

OSET0218

BS-07/04/25-V01

CADILA PHARMACEUTICALS LTD.					
Product Rualadine 10 mg	**Market** Export (Strides Pharma-SA)	**Dimension** 240 x 240 mm			
Item code OSET0218	**Mfg. Location** Dholka	**Component** Leaflet - Back Side	**Change part Layout:** NA		
Substrate: 40 gsm Bilble Paper Pack Insert (Folding size : 120 x 30)					
Superseded item code No. : NA	**Color :** P Black C	**No. of. Colors :** 01	**Pharma Code :** 5974		
Version : 00	**Reason for issue :** New Artwork				