Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: CLOMIDEP
Dosage form: Film-coated tablets
Strength: 25 mg clomipramine hydrochloride /tablet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

CLOMIDEP Film-coated tablets

Clomipramine hydrochloride

Contains sugar: Lactose monohydrate 68,0 mg.

Read all of this leaflet carefully before you start taking CLOMIDEP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLOMIDEP 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 is in this leaflet

1. What CLOMIDEP is and what it is used for

2. What you need to know before you take CLOMIDEP

3. How to take CLOMIDEP

4. Possible side effects

5. How to store CLOMIDEP

6. Contents of the pack and other information

1. What CLOMIDEP is and what it is used for

CLOMIDEP is used to treat depression, including recurrent depressive disorders or major depression.

Other psychological conditions that can be treated with CLOMIDEP are:

- Obsessive compulsive disorders
- Muscular weakness (cataplexy) associated with recurrent attacks of extreme sleepiness (narcolepsy) in adults.

-In children aged above 5 years, CLOMIDEP is used to treat obsessive-compulsive disorders.

2. What you need to know before you take CLOMIDEP

Do not take CLOMIDEP:

- if you are hypersensitive (allergic) to clomipramine, any other tricyclic antidepressants, or to any of the other ingredients in CLOMIDEP
- if you are taking MAO-inhibitors (certain medicines used for depression), a washout period of 14 days is required before you start or stop taking CLOMIDEP due to the potential for severe interactions, severe hypertensive reactions (very high blood pressure), hyperpyretic crisis (extremely high fever), convulsions and fatalities.

Warnings and precautions

Take special care with CLOMIDEP:

- if you have heart disease such as congestive heart failure; blockage of the heart where the electrical signal that controls your heartbeat is partially or completely blocked; irregular or abnormal heartbeats
- if you have narrow angle glaucoma (increased pressure within the eyeball
- if you have difficulty or problems passing urine
- if you have severe liver or kidney disease
- if you are prone to getting convulsions or seizures as a result of brain damage, epilepsy or alcoholism
- if you have a tumour of the adrenal medulla (an area close to the kidneys) in whom the medicine may provoke hypotensive crisis (huge drop in blood pressure).
- if you are thinking about suicide
- if you have schizophrenia or other mental disorders
- if you have any blood disorder
- if you have an overactive thyroid gland
- if you have persisting constipation
- if you have low blood pressure
- if you are diabetic

Your doctor will take these conditions into account before and during your treatment with CLOMIDEP.

Ensure that CLOMIDEP tablets is kept out of reach of children, as relatively small overdoses may be fatal to them.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking CLOMIDEP.

Before and during treatment your doctor may perform tests to assess your medical condition such as blood tests, chest X-rays and ECG (electrocardiogram) examinations.

Families and caregivers should monitor whether the depressed child/patient shows signs of behavioural changes such as unusual anxiety, restlessness, sleeping problems, irritability or aggressiveness, worsening of depression, or any other changes in behaviour or thoughts of suicide.

You should report these symptoms to the patient's doctor especially if they are severe, abrupt in onset or were not part of the patient's presenting symptoms before.

Symptoms such as these may be associated with an increased risk of suicide and indicate a need for very close monitoring and possibly changes in the medication.

CLOMIDEP may cause dry mouth which can increase the risk of tooth decay. Regular dental checks ups is required with long-term treatment.

If you wear contact lenses and experience eye irritation, talk to your doctor.

Before you have surgery or dental treatment tell the doctor or dentist that you are taking CLOMIDEP.

Other medicines and CLOMIDEP

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

CLOMIDEP may increase the effects of alcohol, central nervous system depressants (e.g. barbiturates, benzodiazepines or general anaesthetics), anticholinergics (e.g. atropine, biperiden, levodopa), noradrenaline; adrenaline, amphetamine, nasal drops or local anaesthetics containing sympathomimetics.

CLOMIDEP may decrease the effects of certain antihypertensive medication (bethanidine, debrisoquine, guanethidine and possibly clonidine) and medicines that are highly protein bound (warfarin, digoxin). Patients requiring co-medication for hypertension should therefore be given antihypertensives of a different type.

The effect of CLOMIDEP may be decreased by barbiturates, rifampicin and some anti-epileptics. CLOMIDEP should not be taken together with these medicines.

The use of cimetidine and methylphenidate, together with CLOMIDEP may increase the levels of CLOMIDEP, the dosage of CLOMIDEP may therefore need to be reduced.

Monitoring therapeutic response of tricyclic antidepressants at high dose oestrogen regimens (50 micrograms daily) is recommended and dose adjustments may be necessary.

CLOMIDEP should not be used together with anti-dysrhythmic medicines of the quinidine type (medication for the heart). The risk of arrhythmias may increase if CLOMIDEP is taken with cisapride, halofantrine or other anti-dysrhythmics.

Taking CLOMIDEP together with diuretics may lead to hypokalaemia, which increases the risk of cardiac effects, hypokalaemia must therefore be treated before you start taking CLOMIDEP.

CLOMIDEP must not be taken together with MOA-inhibitors or within two weeks of starting or stopping MAO-inhibitors (see section '**Do not take CLOMIDEP').**

Taking CLOMIDEP with selective serotonin re-uptake inhibitors (e.g. fluoxetine and fluvoxamine), may lead to additive effects on the serotonergic system. For fluoxetine, a washout period of two to three weeks is advised before and after treatment with fluoxetine.

CLOMIDEP with food, drink and alcohol

Alcohol should not be consumed during treatment with CLOMIDEP.

Pregnancy and breastfeeding

Safety in pregnancy has not been established. CLOMIDEP is not recommended for use in pregnant women.

CLOMIDEP should not be used if you are breastfeeding.

If you are pregnant or breastfeeding your baby, 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 CLOMIDEP 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 CLOMIDEP affects them.

At the time of commencement of treatment with CLOMIDEP, do not drive a motor vehicle, climb dangerous heights or operate machinery for at least several days. In these situations, impaired decision making can lead to accidents.

CLOMIDEP contains lactose monohydrate

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

3. How to take CLOMIDEP

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

Always take CLOMIDEP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is 1 tablet (25 mg) 2 to 3 times daily and gradually increased by 1 more tablet (25 mg), as tolerated, every 3 to 4 days up to a total daily dose of 6 tablets (150 mg).

Children (5 years of age and older) and adolescents:

The usual dose is 1 tablet (25 mg) daily during the first two weeks and gradually, increased over several weeks, up to a total daily dose of 3 mg/kg or 8 tablets (200 mg), whichever is smaller.

Your doctor will tell you how long your treatment with CLOMIDEP will last. Do not stop treatment early because the tablets take a while before they start to have an effect. If you have the impression that the effect of CLOMIDEP is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOMIDEP than you should

You may feel drowsy, confused, experience dryness of the mouth, enlarged pupils, vomiting, cyanosis, restlessness, agitation, severe perspiration, hyperactive reflexes, muscle rigidity and convulsions.

An extremely high fever, bowel and bladder paralysis and respiratory and cardiac depression may also occur.

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

If you forget to take CLOMIDEP

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

If you stop taking CLOMIDEP

It is important for you to keep taking CLOMIDEP tablets until your doctor decides to stop them. If you stop taking CLOMIDEP, the depressive conditions may return. This could be dangerous.

4. Possible side effects

CLOMIDEP can have side effects.

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

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

- You have an allergic reaction. The signs may include: shortness of breath, wheezing, difficulty breathing, rash, itching, hives on the skin, swelling of your lips, face or throat.
- You get a headache, dizziness, feel confused or have a seizure.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOMIDEP. 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:

- acute or persistent infections which present as a severe sore throat, fever, fatigue.
- hyperpyrexia (extremely high fever)
- palpitations
- dysrhythmias
- cold sweats
- chest pain
- hypertension
- hypotension (low blood pressure) symptoms of hypotension may include light headedness, dizziness, fainting, blurred vision; fast shallow breathing, fatigue
- severe or persistent diarrhoea
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- oedema.

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:

- anorexia
- increased appetite
- weight gain
- speech disorders

- tremor
- feeling of pins and needles in the fingers or toes
- sudden, brief involuntary twitching or jerking of a muscle or group of muscles
- impaired memory
- Impaired concentration
- manic disorders
- aggravated depression
- restlessness
- seeing or hearing things
- feeling disorientated
- anxiety, nervousness
- nightmares
- yawning
- inability to sleep (insomnia)
- visual changes such as dilation of the pupils with blurred vision or increased eye pressure
- ringing in ears(tinnitus)
- hot flushes
- sweating
- high levels of a family of liver enzymes called transaminases
- pink or red skin rash with blotchy blisters, scaly patches, or raised spots on areas directly exposed to the sun that may burn or itch (photosensitivity)
- muscle weakness
- tension in the muscles
- changed libido, ejaculatory failure, or impotence
- enlargement of breast
- persistent or intermittent milky nipple discharge (galactorrhoea).

Less frequent side effects:

- blood disorders such as:
  - a low platelet level (thrombocytopenia) that causes bleeding into the tissues, bruising, and slow blood clotting after injury
  - increase in the number of eosinophils (eosinophilia) in the blood that causes difficulty in swallowing or food getting stuck in the oesphagus, or a persistent chest pain that does not respond to antacids.
  - purple spots on the skin (purpura).
- nausea (feeling sick), vomiting or diarrhoea
- abdominal cramps or stomach pain
- taste perversion (sour or metallic taste)
- dry mouth
- diarrhoea
- swelling and redness inside the mouth or individual painful sores that can make it uncomfortable to eat (stomatitis)
- hair loss
- urinary retention.

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, pharmacist or nurse. 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 CLOMIDEP.

5. How to store CLOMIDEP

- Store all medicine out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Store in the original package.
- Keep the blister strip in the outer carton.
- Protect from moisture.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- 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 CLOMIDEP contains

The active substance is clomipramine hydrochloride 25 mg.

Preservative: Sodium methylparaben 0,028 % m/m

The other ingredients are:

Tablet core: Brilliant blue lake, colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, purified talc, sodium methyl paraben, sodium starch glycolate.

Film-coat: Acetone, amino methacrylic acid copolymer (Eudragit E 100), brilliant blue lake, isopropyl alcohol, Macrogol 6 000, magnesium stearate, purified talc, sodium lauryl sulphate, titanium dioxide.

What CLOMIDEP looks like and contents of the pack

A blue coloured, circular film-coated tablet having a break line on one side.

CLOMIDEP tablets are available in an aluminium-aluminium strip pack. Five such strips of 10 tablets each are packed in an outer carton.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

a Sun Pharma Company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

CLOMIDEP Filmbedekte tablette

Klomipramienhidrochloried

Bevat suiker: Laktosemonohidraat 68,0 mg.

Lees hierdie hele inligtingsblad aandagtig deur voordat jy begin om CLOMIDEP te neem

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy nog vrae het.
- CLOMIDEP is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, al het hulle dieselfde simptome as jy.

Wat is in hierdie inligtingsblad

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

1. Wat is CLOMIDEP en waarvoor word dit gebruik

CLOMIDEP word gebruik om depressie, insluitende herhaalde depressiewe versteurings of major depressie, te behandel.

Ander psigologiese toestande wat met CLOMIDEP behandel kan word, is:

- Obsessief-kompulsiewe versteurings
- Spierswakheid (katapleksie) wat met herhaalde aanvalle van uitermatige slaperigheid (narkolepsie) by volwassenes gepaard gaan.

- CLOMIDEP word ook gebruik om obsessief-kompulsiewe versteurings by kinders van 5 jaar en ouer te behandel.

2. Wat jy moet weet voordat jy CLOMIDEP neem

Moenie CLOMIDEP neem nie:

- indien jy hipersensitief (allergies) vir klomipramien, enige ander trisikliese antidepressante, of vir enige van die ander bestanddele in CLOMIDEP is
- indien jy MAO-remmers neem (sekere medisynes wat vir depressie gebruik word), word ’n uitwasperiode van 14 dae vereis voordat jy begin of ophou om CLOMIDEP te neem, weens die moontlikheid van hewige interaksies, erge hipertensiewe reaksies (baie hoë bloeddruk), hiperpiretiese krisis (buitensporig hoë koors), konvulsies en sterfte.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met CLOMIDEP:

- indien jy hartsiekte soos kongestiewe hartversaking het; hartsiekte waar die elektriese seine wat jou hartklop beheer gedeeltelik of heeltemal geblok is; onegalige of abnormale hartklop
- indien jy nouhoekgloukoom het (verhoogde druk binne in die oogbal)
- indien jy sukkel of probleme het om urine te laat
- indien jy erge lewer- of niersiekte het
- indien jy geneig is om konvulsies of toevalle te kry as gevolg van breinskade, epilepsie of alkoholisme
- indien jy ’n tumor van die byniermedulla (’n area naby aan die niere) het waar die medisyne ’n hipotensiewe krisis kan ontlok (groot val in bloeddruk)
- indien jy selfdood oorweeg
- indien jy skisofrenie of ander geestesversteurings het
- indien jy enige bloedversteuring het
- indien jy ’n ooraktiewe skildklier het
- indien jy langdurige hardlywigheid het
- indien jy lae bloeddruk het
- indien jy aan diabetes ly.

Jou dokter sal hierdie toestande in oorweging neem voor en tydens jou behandeling met CLOMIDEP.

Maak seker dat CLOMIDEP-tablette gehou word waar kinders dit nie in die hande kan kry nie, aangesien relatief klein oordosisse dodelik vir hulle kan wees.

Indien jy nie seker is of enige van bogenoemde op jou van toepassing is nie, praat met jou dokter of apteker voordat jy CLOMIDEP neem.

Jou dokter kan voor en tydens behandeling toetse laat uitvoer om jou mediese toestand te assesseer, soos bloedtoetse, X-strale van die borskas en EKG- (elektrokardiogram-)ondersoeke.

Families en versorgers moet monitor of die depressiewe kind/pasiënt tekens van gedragsveranderings toon, soos ongewone angstigheid, rusteloosheid, slaapprobleme, prikkelbaarheid of aggressiwiteit, verergering van depressie, of enige ander gedragsveranderings of selfdoodgedagtes.

Jy moet hierdie simptome aan die pasiënt se dokter rapporteer, veral indien dit hewig, met skielike aanvang is of nie aanvanklik deel was van simptome waarmee die pasiënt gepresenteer het nie.

Simptome soos hierdie kan gepaard gaan met ’n verhoogde risiko van selfdood en dui aan dat dit nodig is om die pasiënt streng te monitor en moontlik die medikasie te verander.

CLOMIDEP kan veroorsaak dat die mond droog is, wat die risiko vir tandbederf kan vergroot. Gereelde tandheelkundige opvolgondersoeke is met langtermynbehandeling nodig.

Indien jy kontaklense dra en oogirritasie ondervind, praat met jou dokter daaroor.

Voordat jy chirurgie ondergaan of tandheelkundige behandeling kry, sê vir die dokter of tandarts dat jy CLOMIDEP neem.

Ander medisynes en CLOMIDEP

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)

CLOMIDEP kan die effekte versterk van alkohol, sentralesenuweestelselonderdrukkers (bv. barbiturate, bensodiasepiene of algemene narkose), anticholinergiese middels (bv. atropien, biperideen, levodopa), noradrenalien; adrenalien, amfetamien, neusdruppels of plaaslike anestetika wat simpatomimetika bevat.

CLOMIDEP kan die effekte van sekere antihipertensiewe medikasie (betanidien, debrisokien, guanetidien en moontlik klonidien) en medisynes wat hoogs proteïengebonde is (warfarien, digoksien), verlaag. Pasiënte wat gelyktydig medikasie vir hipertensie gebruik, moet dus ’n ander soort antihipertensiewe middel ontvang.

Die effek van CLOMIDEP kan deur barbiturate, rifampisien en party anti-epileptiese middels verminder word. CLOMIDEP behoort nie saam met hierdie medisynes geneem word nie.

Die gelyktydige gebruik van simetidien en metielfenidaat saam met CLOMIDEP kan die vlakke van CLOMIDEP verhoog, gevolglik kan dit nodig wees om die dosis van CLOMIDEP te verlaag.

Dit word aanbeveel dat die terapeutiese respons van trisikliese antidepressante by hoë-dosis estrogeen regimens (50 mikrogram daagliks) gemonitor word en dit mag nodig wees om die dosis aan te pas.

CLOMIDEP moenie saam met kinidien-tipe antidisritmiese medisynes gebruik word nie (medikasie vir die hart). Die risiko van aritmieë kan verhoog indien CLOMIDEP saam met sisapried, halofantrien of ander antidisritmiese middels gebruik word.

Wanneer CLOMIDEP saam met diuretika geneem word, kan dit tot hipokalemie lei, wat die risiko van kardiale effekte verhoog, dus behoort hipokalemie behandel te word voordat jy begin om CLOMIDEP te neem.

CLOMIDEP moenie gebruik word saam met MOA-remmers of binne twee weke nadat jy begin of opgehou het om MAO-remmers te neem nie (sien afdeling **'Moenie CLOMIDEP neem nie'**).

Die neem van CLOMIDEP saam met selektiewe serotonienheropnameremmers (bv. fluoksetien en fluvoksamien), kan tot additiewe effekte op die serotonergiese stelsel lei. Vir fluoksetien word 'n uitwasperiode van twee tot drie weke voor en na behandeling met fluoksetien aangeraai.

CLOMIDEP met kos, drinkgoed en alkohol

Moenie alkohol inneem terwyl jy met CLOMIDEP behandel word nie.

Swangerskap en borsvoeding

Dit is nie vasgestel of dit veilig is om tydens swangerskap gebruik te word nie. CLOMIDEP word nie vir gebruik by swanger vrouens aanbeveel nie.

Jy behoort nie CLOMIDEP te gebruik indien jy borsvoed nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Bestuur en die gebruik van masjiene

Dit is nie altyd moontlik om te voorspel tot watter mate CLOMIDEP met ’n pasiënt se daaglikse aktiwiteite mag inmeng nie. Pasiënte moet verseker dat hulle nie bogenoemde aktiwiteite uitvoer nie, totdat hulle weet tot watter mate CLOMIDEP hulle affekteer.

Wanneer behandeling met CLOMIDEP begin word, moet jy vir ten minste ’n paar dae nie ’n motorvoertuig bestuur, gevaarlike hoogtes bestyg of masjinerie hanteer nie. Belemmerde besluitneming kan onder hierdie omstandighede tot ongelukke lei.

CLOMIDEP bevat laktosemonohidraat

Indien jou dokter jou ingelig het dat jy vir sekere suikers onverdraagsaam is, kontak jou dokter voordat jy hierdie medisyne neem.

3. Hoe om CLOMIDEP te neem

Moenie medisyne wat vir jou voorgeskryf is, met iemand anders deel nie.

Neem CLOMIDEP altyd presies soos wat jou dokter of apteker vir jou aangedui het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes:

Die gebruiklike dosis is 1 tablet (25 mg) 2 tot 3 keer daagliks, wat dan geleidelik verhoog word met nog 1 tablet (25 mg), soos verdra, elke 3 tot 4 dae tot ’n totale daagliks dosis of 6 tablette (150 mg).

Kinders (5 jaar en ouer) en adolessente:

Die gebruiklike dosis is 1 tablet (25 mg) daagliks tydens die eerste twee weke, wat oor ’n paar weke geleidelik verhoog word, tot ’n totale daaglikse dosis van 3 mg/kg of 8 tablette (200 mg), watter een ook al die laagste is.

Jou dokter sal vir jou sê hoe lank jou behandeling met CLOMIDEP sal duur. Moenie behandeling voortydig staak nie, want die tablette neem ’n tydjie voordat dit begin om ’n uitwerking te hê. Indien jy die indruk kry dat die effek van CLOMIDEP te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer CLOMIDEP geneem het as wat jy moet

Jy kan die volgende ondervind: lomerigheid, verwardheid, droë mond, verwyde pupille, braking, sianose, rusteloosheid, agitasie, erge sweting, hiperaktiewe reflekse, spierstyfheid en konvulsies.

'n Buitensporig hoë koors, verlamming van die dikderm en blaas, en onderdrukking van asemhaling en hartfunksie kan ook voorkom.

In geval van oordosering, konsulteer jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om CLOMIDEP te neem

Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

Indien jy ophou om CLOMIDEP te neem

Dit is belangrik dat jou aanhou om CLOMIDEP-tablette te neem totdat jou dokter besluit dat jy kan ophou. Indien jy ophou om CLOMIDEP te neem, kan die depressiewe toestand terugkeer. Dit kan gevaarlik wees.

4. Moontlike newe-effekte

CLOMIDEP kan newe-effekte hê.

Nie alle newe-effekte wat vir CLOMIDEP gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy CLOMIDEP neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende simptome voorkom, hou op om CLOMIDEP te neem en sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:

- Jy het 'n allergiese reaksie. Die tekens kan kortasemheid, gehyg, moeisame asemhaling, uitslag, gejeuk, galbulte op die vel, swelling van jou lippe, gesig of keel insluit.
- Jy kry hoofpyn, voel duiselig, verward of kry 'n toeval.

Hierdie is baie ernstige newe-effekte. Jy mag 'n ernstige reaksie op CLOMIDEP gehad het as jy dit het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- akute of volgehoue infeksies wat presenteer as 'n baie seer keel, koors, moegheid.
- hiperpireksie (buitensporig hoë koors)

- palpitasies
- disritmieë
- kouesweet
- pyn in die borskas
- hipertensie
- hipotensie (lae bloeddruk), simptome van hipotensie kan lighoofdigheid, duiseligheid, floute en dowwe visie insluit; vinnige vlak asemhaling, moegheid
- strawwe of aanhoudende diarree
- vergeling van die vel en oë, donkerkleurige urine en moegheid, wat simptome van lewerprobleme kan wees
- edeem.

Hierdie is ernstige newe-effekte. Jy mag dringend mediese bystand nodig hê.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- anoreksie
- toename in aptyt
- gewigstoename
- spraaksteurings
- tremor
- naalde-en-spelde-gevoel in die vingers of tone
- skielike, kortstondige, onwillekeurige trekkings of rukkings van ’n spier of groep spiere
- belemmerde geheue
- belemmerde konsentrasie
- maniese steurings
- verergerde depressie
- rusteloosheid
- sien of hoor goed
- voel gedisoriënteerd

- angstigheid, senuweeagtigheid
- nagmerries
- gaap
- kan nie slaap nie (insomnia)
- visuele veranderings soos verwyding van die pupille met dowwe visie of verhoogde druk in die oog
- gesuis in die ore (tinnitus)
- warm gloede
- sweting
- hoë vlakke van ’n groep lewerensieme genaamd transaminases
- pienk of rooi veluitslag met vlekkerige blase, skubberige kolle, of opgehewe kolle op dele wat aan direkte sonlig blootgestel is, wat kan brand of jeuk (fotosensitiwiteit)
- spierswakheid
- spanning in die spiere
- veranderde libido, probleme met ejakulasie, of impotensie
- borsvergroting
- aanhoudende of afwisselende melkerige afskeiding uit die tepels (galaktorree).

Newe-effekte wat minder dikwels voorkom:

- bloedversteurings soos:
  - ’n lae plaatjietelling (trombositopenie) wat bloeding in die weefsel in, kneusing en stadige bloedklomping na besering veroorsaak
  - toename in die aantal eosinofiele (eosinofilie) in die bloed, wat probleme met sluk of dat kos vassit in jou slukderm veroorsaak, of ’n aanhoudende pyn in die bors wat nie op behandeling met teensuurmiddels reageer nie
  - pers kolletjies op die vel (purpura).
- naarheid (voel mislik), braking of diarree
- krampe in die buik of maagpyn
- smaakperversie (suur- of metaalsmaak)
- droë mond

- diarree
- swelling en rooiheid binne in die mond of afsonderlike pynlike sere wat dit ongemaklik kan maak om te eet (stomatitis)
- haarverlies
- urienterughouding.

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

Rapportering van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van CLOMIDEP te verskaf.

5. Hoe om CLOMIDEP te bewaar

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar by of benede 25 °C op ’n koel, droë plek, beskerm teen lig.
- Bewaar in die oorspronklike verpakking.
- Hou die stulpstrook in die buitenste karton.
- Beskerm teen vog.
- Moenie in ’n badkamer bêre nie.
- Moenie gebruik ná die vervaldatum wat op die karton voorkom nie. Die vervaldatum verwys na die laaste dag van daardie maand.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting

Wat CLOMIDEP bevat

Die aktiewe bestanddeel is 25 mg klomipramienhidrochloried.

Preserveermiddel: Natriummetielparabeen 0,028 % *m/m.*

Die ander bestanddele is:

Tabletkern: Brilliant Blue-lak, kolloïdale anhidriese silika, laktosemonohidraat, magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, gesuiwerde talkum, natriummetielparabeen, natriumstyselglikolaat.

Filmlagie: Asetoon, amino-metakrielsuur-kopolimeer (Eudragit E 100), Brilliant Blue-lak, isopropielalkohol, Makrogol 6 000, magnesiumstearaat, gesuiwerde talkum, natriumlourielsulfaat, titaandioksied.

Hoe CLOMIDEP lyk en inhoud van die verpakking

'n Blou, ronde, filmbedekte tablet met 'n breeklyn aan die een kant.

Aluminium-aluminiumstulpstrook.

CLOMIDEP-tablette is beskikbaar in 'n aluminium-aluminiumstulpstrook. Vyf stulpstroke met 10 tablette elk word in 'n buitekarton verpak.

AL/PVC koudgevormde stulpverpakking

CLOMIDEP tablette is beskikbaar in 'n PVC koudgevormde stulpverpakking. Vyf sulke stulpstroke van 10 tablette elk word in 'n buitekarton verpak.

Nie alle verpakkingstipes mag gelyktydig bemark word nie.

Houer van registrasiesertifikaat

Ranbaxy Pharmaceuticals (Edms.) Bpk.

Lautreweg 14, Stormill Uitbr. 1

Roodepoort 1724

Suid-Afrika

Hierdie inligtingsblad is laas hersien op

13 Mei 2022

Registrasienommer

35/1.2/0253