MODAFINIL 100 IPHARMA

Scheduling Status:
S5

MODAFINIL 100 IPHARMA, tablets
Modafinil
Contains sugar (lactose monohydrate 49,4 mg per tablet)

Read all of this leaflet carefully before you start taking MODAFINIL IPHARMA.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MODAFINIL 100 IPHARMA 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 MODAFINIL IPHARMA is and what it is used for:
MODAFINIL IPHARMA contains the active substance modafinil. Modafinil is a central nervous system (CNS) stimulant which increases alertness.
MODAFINIL IPHARMA can be taken by adults who suffer from narcolepsy to help them to stay awake.
Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations (sleep attacks), which is caused by the brain's inability to regulate sleep-wake cycles normally.

2. What you need to know before you take Modafinil 100 iPharma:
Do not take Modafinil 100 iPharma if:
- you are hypersensitive (allergic) to modafinil or any of the other ingredients of MODAFINIL IPHARMA (listed in section 6)
- you suffer from major anxiety
- you are a child or adolescent under the age of 16 years
- you suffer from kidney failure / impairment
- you have uncontrolled, moderate to severe high blood pressure (hypertension)
- you have an irregular heartbeat

Warnings and precautions:
Take special care with MODAFINIL IPHARMA:
- If you are taking MODAFINIL IPHARMA you should be seen by a specialist on a regular basis to be clinically assessed
- You should notify your doctor immediately if you develop any kind of rash, hives or any allergic reaction as there have been reports of rare cases of a severe life-threatening allergic reaction (Stevens Johnson syndrome)
- If you suffer from major anxiety MODAFINIL IPHARMA should only be administered in a specialist unit under the care of a specialist
- If you have a history of psychosis MODAFINIL IPHARMA should be used with caution
- If you suffer from high blood pressure your heart rate should be monitored
- You should not take MODAFINIL IPHARMA if you have a history of heart enlargement, abnormal/irregular heartbeats, changes in your ECG or other heart problems as the risk of developing similar effects may be increased with the use of MODAFINIL IPHARMA
- If you had a recent history of heart attack or unstable chest pain, you should be treated with caution under close supervision of your doctor
- MODAFINIL IPHARMA can cause wakefulness and therefore you should be cautious if taking MODAFINIL IPHARMA if you suffer from staying asleep
- If you are using hormonal contraceptives, you should use alternative or additional methods of contraception during and for one month after you stop taking MODAFINIL IPHARMA as modafinil may reduce the effectiveness of hormonal contraceptives. Continuation of the oral contraceptive for two cycles after stopping MODAFINIL IPHARMA is necessary for adequate contraception
- If you suffer from severe liver impairment you should take a lower dose of MODAFINIL IPHARMA
- If you are an elderly patient a lower dose should be prescribed by your doctor as your kidney and liver function may be lower
- As with other central nervous system stimulants, there is the possibility of dependence with the long-term use of MODAFINIL IPHARMA
- You should not take any alcohol while using MODAFINIL IPHARMA as the combination of these two substances have not been tested

Children and adolescents
MODAFINIL IPHARMA should not be given to individuals under the age of 16.

Other medicines and MODAFINIL IPHARMA
Always tell your healthcare provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
- MODAFINIL IPHARMA may increase blood levels and strengthen the effect of medicines such as diazepam (used for anxiety), phenytoin (used for epilepsy), omeprazole (used for acid reflux, indigestion or ulcers) and propranolol (used for high blood pressure or heart problems) when used in combination.
- Blood levels of medicine used to treat epilepsy should be monitored with care with the combined use with MODAFINIL IPHARMA as blood levels of the anti-epileptic medicine may change. If you are using a medicine called phenytoin used to treat fits and seizures, you should be monitored by your doctor for signs of phenytoin toxicity.
- The effectiveness of oral contraceptives may be impaired by MODAFINIL IPHARMA. An oral contraceptive product containing 50 micrograms or more of ethinyl oestradiol should be taken. Continuation of the oral contraceptive for two cycles after stopping MODAFINIL IPHARMA is necessary for adequate contraception.
- Blood levels and the effect of certain types of medicine like tricyclic antidepressants (e.g. amitriptyline) and selective serotonin reuptake inhibitors (e.g. citalopram or fluoxetine) used in patients with a certain enzyme deficiency (CYP2D6) for the treatment of depression, may be increased when used in combination with MODAFINIL IPHARMA. Your doctor will have to adjust your dose.
- If you are using MODAFINIL IPHARMA in combination with warfarin, it is recommended that your doctor monitor your prothrombin times as a precaution for the first several months and thereafter whenever MODAFINIL IPHARMA dosing is changed.
- MODAFINIL IPHARMA may lead to lower blood levels and weakening of the effect of ciclosporin (used in organ transplants, arthritis or psoriasis), antiviral medicines for the treatment of HIV (protease inhibitors e.g. indinavir or ritonavir), medicines for anxiety and sleeping problems (e.g., buspirone, triazolam or midazolam), medicines for high blood pressure and heart problems (calcium channel blockers e.g. amlodipine or verapamil), and cholesterol-lowering medicines (statins e.g. atorvastatin or simvastatin).
- Other medicines that increase the effect of an enzyme system known as cytochrome P-450 isoenzymes such as carbamazepine and phenobarbital used for epilepsy, could decrease the blood levels and weaken the effect of MODAFINIL IPHARMA.

MODAFINIL IPHARMA with food and alcohol
Food may delay the absorption of MODAFINIL IPHARMA by approximately one hour, but it does not affect the availability of the medicine in your body.
Use with caution if you have a history of alcohol or drug abuse.

Pregnancy, breastfeeding and fertility
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 MODAFINIL IPHARMA.
Do not take MODAFINIL IPHARMA if you are pregnant or breastfeeding your baby.
MODAFINIL IPHARMA is suspected to cause birth defects if taken during pregnancy.
Talk to your doctor about the birth control methods that will be right for you while you are taking MODAFINIL IPHARMA (and for two months after stopping).

Driving and using machines
MODAFINIL IPHARMA can cause blurred vision or dizziness. MODAFINIL IPHARMA could affect your ability to drive or operate machinery and you should not engage in such activities until the effect of the medicine on you are clear.
It is not always possible to predict to what extent MODAFINIL IPHARMA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which MODAFINIL IPHARMA affects you.

3. How to take MODAFINIL IPHARMA
Do not share medicines prescribed for you with any other person.
Always take MODAFINIL IPHARMA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose of MODAFINIL IPHARMA is 200 mg/day, taken in the morning as a single dose.
Doses of 400 mg/day, given as a single dose, is well tolerated, but there is no consistent evidence that this dose offers additional benefit beyond that of the 200 mg dose.
If you are an elderly patient your dose may have to be reduced by your doctor
If you suffer from liver failure your dose will have to be reduced by half ((100 to 200 mg/day).
Your doctor will tell you how long your treatment with MODAFINIL IPHARMA will last. If you have the impression that the effect of MODAFINIL IPHARMA is too strong or too weak, tell your doctor or pharmacist.

If you take more MODAFINIL IPHARMA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
If you take too many tablets you may feel sick, restless, disorientated, confused, agitated, anxious or excited. You may also have difficulty sleeping, diarrhoea, hallucinations, chest pain, a change in the speed of your heartbeat or an increase in blood pressure.

If you forget to take MODAFINIL IPHARMA
If you forget to take your medicine, take the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

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

If any of the following happens, stop taking MODAFINIL IPHARMA 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 all very serious side effects. If you have them, you may have had a serious reaction to MODAFINIL IPHARMA. 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:
- you notice a skin rash or itching (especially if it affects your whole body). Severe rashes may cause blistering or peeling of the skin, ulcers in your mouth, eyes, nose or genitals. You may also have high temperature and abnormal blood test results.
- you feel any change in your mental health and wellbeing. *The signs may include:*
  - mood swings or abnormal thinking
  - aggression or hostility
  - forgetfulness or confusion
  - feeling of extreme happiness
  - over excitement or hyperactivity
  - anxiety or nervousness
  - depression, suicidal thoughts or behaviour
  - agitation or psychosis (a loss of contact with reality which may include delusions or sensing things that are not real), feeling detached or numb, or personality disorder.

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
- decreased appetite
- sleeplessness
- headache, dizziness
- weakness, numbness or tingling of the hands or feet (pins and needles)
- blurred vision
- awareness of your heartbeat, which may be faster than normal
- widening of blood vessels
- stomach pain, nausea, dry mouth, diarrhoea, indigestion, constipation
- chest pain
- lack of energy
- abnormal blood test results showing how your liver is working (increased liver enzymes)

Less frequent side effects
- inflammation /infection of the throat, sinus infection
- increase in white blood cells known as eosinophilia
- a low level of white blood cells in the blood, which can interfere with the ability to fight infection
- high blood sugar, high cholesterol, increased appetite
- sleep disorder, abnormal dreams, decreased sex drive, hallucinations
- difficulty moving muscles smoothly or other movement problems, muscle tension, coordination problems
- loss of memory, migraine, a spinning sensation (vertigo)
- a decreased sense of touch or sensation, speech disorder, altered or impaired sense of taste
- abnormal vision, dry eye, lazy eye
- abnormal heart beat, irregular heartbeat, abnormally slow heart rate
- low or high blood pressure
- increased cough, asthma or shortness of breath, nose bleeds, runny nose
- flatulence, heartburn, mouth sores, inflammation of the tongue, vomiting, difficulty swallowing
- skin rash, acne or itchy skin
- sweating
- back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching or tremor
- abnormal urine, more frequent urination, abnormal ejaculation
- menstrual disorder
- swelling of the legs and arms, thirst
- abnormal ECG and weight increase or decrease

Side effects with unknown frequency
- infection, low body temperature, flu syndrome
- an increase in the number of white cells in the blood, especially during an infection
- deficiency in the number or quality of red blood cells in your body
- a sudden, brief loss of voluntary muscle tone triggered by strong emotions such as laughter
- ear pain, ear disorders
- inflammation of the lining of bronchial tubes, which carry air to and from the lungs, lung infection
- tooth disorders, vomiting, inflamed gums, loss of appetite
- a discoloration of the skin resulting from bleeding underneath, typically caused by bruising.
- itchy skin, dry skin, skin disorders, chronic immune –mediated skin disease (psoriasis)
- an infection in any part of the urinary system, the kidneys, bladder or urethra, pus in the urine, blood in the urine, bladder inflammation
- painful menstruation
- increased liver enzymes (AST)
- accidental injury

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 the South African Health Products Regulatory Authority (SAHPRA) via the *"6.04 Adverse Drug Reaction Reporting Form"*, found online under SAHPRA's publications. By reporting side effects, you can help provide more information on the safety of Modafinil 100 iPharma.

5. How to store MODAFINIL IPHARMA:
Store all medicine out of reach of children.
Store at or below 25 °C.
Store in the original packaging until required for use.
Do not use the tablets after the expiry date shown on the container.
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 MODAFINIL IPHARMA contains:
The active ingredient is modafinil. Each tablet contains 100 mg modafinil.
The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K29/32, pregelatinised starch, talc.

What MODAFINIL IPHARMA looks like and contents of the pack:
White, circular, biconvex tablet and without irregularities, 9 mm.
MODAFINIL IPHARMA tablets are packed in heat-sealed PVC – Aluminium blister packs.
Blister strips of MODAFINIL IPHARMA tablets are packed together with the leaflets in cardboard cartons of 30 tablets.

Holder of Certificate of Registration:
iPharma (Pty) Ltd
124 Elevation Avenue, Randjesfontein
Midrand, 1683, South Africa
Tel. no.: (011) 314 2366

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MODAFINIL 100 IPHARMA

Skeduleringstatus:
S5

MODAFINIL 100 IPHARMA, tablette
Modafiniel
Bevat suiker (49,4 mg laktosemonohidraat per tablet)

Lees hierdie hele blad noukeurig deur voordat u begin om MODAFINIL IPHARMA te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- MODAFINIL IPHARMA is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

WAT IN HIERDIE BLAD IS:

1. Wat MODAFINIL IPHARMA is en waarvoor dit gebruik word
MODAFINIL IPHARMA bevat die aktiewe bestanddeel modafiniel. Modafiniel is 'n stimulant van die sentrale senuweestelsel (SSS) wat wakkerheid verhoog.
MODAFINIL IPHARMA kan deur volwassenes wat aan narkolepsie ly, gebruik word om hulle te help om wakker te bly.
Narkolepsie is 'n toestand wat oormatige slaperigheid in die dag veroorsaak en 'n neiging om skielik aan die slaap te raak in onvanpaste situasies (slaapaanvalle), wat veroorsaak word deur die brein se onvermoë om slaap-wakker-siklusse normaalweg te reguleer.

2. Wat u moet weet voordat u MODAFINIL IPHARMA drink
Moenie MODAFINIL IPHARMA drink nie as:
- u hipersensitief (allergies) vir modafiniel of vir enige van die ander bestanddele van MODAFINIL IPHARMA (gelys in afdeling 6) is.
- u erge angs het.
- 'n kind of adolessent jonger as 16 jaar is.
- u swak nier- of lewerfunksie het.
- u onbeheerde, matige tot erge hoë bloeddruk (hipertensie) het.
- u 'n onreëlmatige hartklop het.

Waarskuwings en voorsorgmaatreëls:
Wees besonder versigtig met MODAFINIL IPHARMA:
- As u MODAFINIL IPHARMA drink, moet u op 'n gereelde basis deur 'n spesialis gesien word om klinies beoordeel te word.
- U moet u dokter dadelik in kennis stel as u enige soort veluitslag, galbulte of enige allergiese reaksie ontwikkel, aangesien daar verslae was van seldsame gevalle van 'n ernstige lewensgevaarlike allergiese reaksie (Stevens Johnson-sindroom)
- As u aan erge angs ly, moet MODAFINIL IPHARMA slegs in 'n spesialiseenheid onder die sorg van 'n spesialis toegedien word.
- As u 'n geskiedenis van psigose het, moet MODAFINIL IPHARMA versigtig gebruik word.
- As u aan hoë bloeddruk ly, moet u hartklop gemonitor word.
- U moet nie MODAFINIL IPHARMA drink as u 'n geskiedenis van vergroting van die hart, abnormale/onreëlmatige hartklop, veranderinge in u EKG of ander hartprobleme het nie, aangesien die risiko om soortgelyke effekte te ontwikkel deur die gebruik van MODAFINIL IPHARMA verhoog kan word.
- As u 'n onlangse geskiedenis van hartaanval of onstabiele borspyn gehad het, moet u versigtig onder noukeurige toesig van u dokter behandel word
- MODAFINIL IPHARMA kan wakkerheid veroorsaak en daarom moet u versigtig wees as u MODAFINIL IPHARMA drink as u sukkel om aan die slaap te bly.
- As u hormonale voorbehoedmiddels gebruik, moet u tydens en vir een maand nadat u opgehou het om MODAFINIL IPHARMA te gebruik alternatiewe of bykomende metodes van voorbehoeding gebruik, aangesien modafiniel die doeltreffendheid van hormonale voorbehoed middels kan verlaag. Vir voldoende kontrasepsie is dit nodig dat die orale voorbehoedmiddel steeds vir twee siklusse nadat MODAFINIL IPHARMA gestaak is, gedrink moet word.
- As u aan erge lewerversaking ly, moet u 'n laer dosis MODAFINIL IPHARMA drink.
- As u 'n bejaarde pasiënt is, moet 'n laer dosis deur u dokter voorgeskryf word aangesien u nier- en lewerfunksie laer kan wees
- Soos met ander stimulante van die sentrale senuweestelsel, is daar die moontlikheid van afhanklikheid met die langtermyngebruik van MODAFINIL IPHARMA
- U moet nie alkohol drink terwyl u MODAFINIL IPHARMA gebruik nie, aangesien die kombinasie van hierdie twee stowwe nie getoets is nie.

Kinders en adolessente
MODAFINIL IPHARMA moet dit nie aan kinders jonger as 16 jaar gegee word nie.

Ander medisyne en MODAFINIL IPHARMA
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
- MODAFINIL IPHARMA kan bloedvlakke verhoog en die effek van medisyne soos diasepaam (gebruik vir angs), fenitoïen (gebruik vir epilepsie), omeprasool (gebruik vir sooibrand, slegte spysvertering of maagsere) en propranolol (gebruik vir hoë bloeddruk of hartprobleme) versterk wanneer dit saam gebruik word.
- Bloedvlakke van medisyne om epilepsie te behandel, moet versigtig gemonitor word wanneer dit saam met MODAFINIL IPHARMA gebruik word aangesien bloedvlakke van die anti-epileptiese medisyne kan verander. As u 'n middel genaamd fenitoïen gebruik om toevalle en stuiptrekkings te behandel, moet u deur u dokter gemonitor word vir tekens van fenitoïentoksisiteit.
- Die effektiwiteit van orale voorbehoedmiddels kan deur MODAFINIL IPHARMA verlaag word. 'n Orale voorbehoedmiddel wat 50 mikrogram of meer etinielestradiol bevat, moet gebruik word. Voortsetting van die orale voorbehoedmiddel vir twee siklusse nadat MODAFINIL IPHARMA gestaak is, is vir voldoende kontrasepsie nodig.
- Bloedvlakke en die effek van sekere soorte medisyne soos trisikliese antidepressante (bv. amitriptilien) en selektiewe serotonienheropnameremmers (bv. sitalopraam of fluoksetien) wat vir die behandeling van depressie gebruik word deur pasiënte met 'n sekere ensiemtekort (CYP2D6), kan hoër wees wanneer dit saam met MODAFINIL IPHARMA gebruik word. Dit mag wees dat u dokter u dosis moet aanpas.
- As u MODAFINIL IPHARMA saam met warfarien gebruik, word dit aanbeveel dat u dokter vir die eerste paar maande en daarna wanneer MODAFINIL IPHARMA-dosis verander word, u protrombientye as 'n voorsorgmaatreël monitor.
- MODAFINIL IPHARMA kan tot laer bloedvlakke en verswakking van die effek lei van siklosporien (gebruik tydens orgaanoorplantings, en vir artritis of psoriase), antivirale medisyne vir die behandeling van MIV (proteaseremmers bv. indinavir of ritonavir), medisyne vir angs en slaapprobleme (bv., buspiroon, triasolaam of midasolaam), medisyne vir hoë bloeddruk en hartprobleme (kalsiumkanaalblokkeerders bv. amlodipien of verapamil), en cholesterolverlagende medisyne (statiene bv. atorvastatien of simvastatien).
- Ander medisyne wat die effek van 'n ensiemstelsel bekend as sitochroom P-450 isoënsieme verhoog, soos karbaamasepien en fenobarbitoon wat vir epilepsie gebruik word, kan die bloedvlakke van MODAFINIL IPHARMA verlaag en die effek verswak.

Gebruik van MODAFINIL IPHARMA saam met voedsel en alkohol
Voedsel kan die absorpsie van MODAFINIL IPHARMA met ongeveer een uur vertraag, maar dit beïnvloed nie die beskikbaarheid van die medisyne in die liggaam nie.
Geruik versigtig as u 'n geskiedenis van alkohol of dwelmmisbruik het.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u MODAFINIL IPHARMA drink.
Moenie MODAFINIL IPHARMA drink as u swanger is of u baba borsvoed nie.
Dit word vermoed dat MODAFINIL IPHARMA geboortedefekte veroorsaak as dit tydens swangerskap gedrink word.
Praat met u dokter oor die metodes van voorbehoeding wat reg vir u sal wees terwyl u MODAFINIL IPHARMA drink (en vir twee maande nadat u dit gestaak het).

Motorbestuur en gebruik van masjinerie
MODAFINIL IPHARMA kan versteurde visie of duiseligheid veroorsaak. MODAFINIL IPHARMA kan u vermoë om te bestuur of masjinerie te hanteer beïnvloed en totdat die effek van die medisyne op u bekend is, moet u nie aan sulke aktiwiteite deelneem nie.
Dit is nie altyd moontlik om te voorspel tot watter mate MODAFINIL IPHARMA met u daaglikse aktiwiteite kan inmeng nie. Totdat u weet hoe MODAFINIL IPHARMA u beïnvloed, moet u seker maak dat u nie 'n voertuig bestuur of masjiene hanteer nie.

3. Hoe om MODAFINIL IPHARMA te drink
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Drink MODAFINIL IPHARMA altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
Die gewone dosis MODAFINIL IPHARMA is 200 mg/dag, in die oggend as 'n enkele dosis geneem.
Dosisse van 400 mg/dag, gegee as 'n enkele dosis, word goed verdra, maar daar is geen konsekwente bewyse dat hierdie dosis bykomende voordele bo dié van die 200 mg-dosis bied nie.
As u 'n bejaarde pasiënt is, moet u dokter u dosis dalk verlaag.
As u aan lewerversaking ly, moet u dosis met die helfte verminder word (100 tot 200 mg/dag).
U dokter sal vir u sê hoe lank u behandeling met MODAFINIL IPHARMA sal duur. Sê vir u dokter of apteker as u die indruk het dat die effek van MODAFINIL IPHARMA te sterk of te swak is.

As u meer MODAFINIL IPHARMA gedrink het as wat u moes
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
As u te veel tablette drink, kan u naar, rusteloos, gedisoriënteerd, verward, opgewonde, angstig of opgewonde voel. U kan ook sukkel om te slaap of diarree, hallusinasies, borspyn, 'n verandering in die tempo van u hartklop of 'n toename in bloeddruk ervaar.

As u vergeet om MODAFINIL IPHARMA te drink
As u vergeet om 'n dosis te drink, moet u die volgende dosis op die gewone tyd drink. Moenie 'n dubbele dosis gebruik om vir vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte
MODAFINIL IPHARMA kan newe-effekte hê.
Nie al die newe-effekte wat vir MODAFINIL IPHARMA aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar terwyl u MODAFINIL IPHARMA drink, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om MODAFINIL IPHARMA te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:
- swelsel van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige reaksie op MODAFINIL IPHARMA gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
- 'n Veluitslag of jeuk (veral as dit die hele liggaam aantas). Erge uitslag kan blase of afskilfering van die vel, sere in die mond, op die oë, neus of geslagsdele veroorsaak. U kan ook hoë temperatuur en abnormale uitslae van bloedtoets hê.
- U voel 'n verandering in u geestesgesondheid en welsyn. *Die tekens kan die volgende wees:*
  - buierigheid of abnormale denke
  - aggressie of vyandigheid
  - vergeetagtigheid of verwardheid
  - gevoel van uiterste geluk
  - ooropgewondenheid of hiperaktiwiteit
  - angstigheid of senuagtigheid
  - depressie, selfdoodgedagtes en -gedrag
  - agitasie of psigose ('n verlies van kontak met die werklikheid wat delusies kan insluit of voel dinge aan wat nie werklik is nie), voel los van jouself of afgestomp, of persoonlikheidsversteuring.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Algemene newe-effekte
- swak eetlus
- slaaploosheid
- hoofpyn, duiseligheid
- swakheid, gevoelloosheid of tinteling in die hande of voete (naalde en spelde)
- dowwe visie
- bewustheid van jou hartklop, wat vinniger as normaal kan wees
- verwyding van die bloedvate
- maagpyn, naarheid, droë mond, diarree, slegte spysvertering, hardlywigheid
- pyn in die borskas
- gebrek aan energie
- abnormale uitslae van bloedtoetse wat wys hoe die lewer werk (hoër vlakke lewerensieme)

Minder algemene newe-effekte
- inflammasie/infeksie van die keel, sinusinfeksie
- toename in die aantal witbloedselle, bekend as eosinofilie
- 'n lae vlak van witbloedselle in die bloed, wat die vermoë om infeksie te beveg, kan belemmer
- hoë bloedsuikervlakke, hoë cholesterolvlakke, groot eetlus
- slaapversteuring, abnormale drome, laer seksdrang, hallusinasies
- probleme om spiere glad te beweeg of ander bewegingsprobleme, spierspanning, koördinasieprobleme
- geheueverlies, migraine, 'n draaiende sensasie (vertigo)
- 'n laer sin van aanraking of sensasie, spraakversteuring, veranderde of verswakte smaaksin
- abnormale visie, droë oë, lui oog
- abnormale hartklop, onreëlmatige hartklop, abnormaal stadige hartklop
- lae of hoë bloeddruk
- meer hoes, asma of kortasemheid, neusbloeding, loopneus
- winderigheid, sooibrand, mondsere, ontsteking van die tong, braking, probleme om te sluk
- veluitslag, aknee of jeukerige vel
- sweet
- rugpyn, nekpyn, spierpyn, spierswakheid, beenkrampe, gewrigspyn, spiertrekkings of bewing
- abnormale urien, meer dikwelse urinering, abnormale ejakulasie
- menstruasie-afwykings
- swelling van die bene en arms, dors
- abnormale EKG en gewigstoename of -afname

Newe-effekte met onbekende frekwensie
- infeksie, lae liggaamstemperatuur, griepsindroom
- 'n afname in die aantal selle in die bloed wat infeksie beveg
- tekort aan die aantal of kwaliteit van rooibloedselle in die liggaam
- 'n skielike, kort verlies van vrywillige spiertonus veroorsaak deur sterk emosies soos lag
- oorpyn, oorafwykings
- inflammasie van die voering van die lugweg, wat lug na en van u longe vervoer, longinfeksie
- tandafwykings, braking, ontsteekte tandvleis, verlies aan eetlus
- 'n verkleuring van die vel as gevolg van bloeding daaronder, gewoonlik veroorsaak deur kneusplekke
- jeukerige vel, droë vel, velafwykings, chroniese immuungemedieerde velsiekte (psoriase)
- 'n infeksie in enige deel van die urienstelsel, die niere, blaas of uretra, etter in die urien, bloed in die urien, blaasontsteking
- pynlike menstruasie
- hoë vlakke lewerensieme (AST)
- onopsetlike besering

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by die Suid-Afrikaanse reguleringsowerheid vir gesondheidsprodukte ("South African Health Products Regulatory Authority - SAHPRA") aanmeld met die toepaslike vorm, naamlik *"6.04 Adverse Drug Reaction Reporting Form"* wat aanlyn by SAHPRA se publikasies gekry kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van MODAFINIL IPHARMA te gee.

5. Hoe om MODAFINIL IPHARMA te stoor
Hou alle medisyne buite bereik van kinders.
Bêre by of onder 25 °C.
Bêre in die oorspronklike houer totdat dit vir gebruik benodig word.
Moenie die tablette na die vervaldatum op die karton gebruik nie.
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting
Wat MODAFINIL IPHARMA bevat
Die aktiewe bestanddeel is modafiniel. Elke tablet bevat 100 mg modafiniel.
Ander bestanddele is natriumkruiskarmellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, povidoon K29/32, voorafgeswelde stysel en talk.

Hoe MODAFINIL IPHARMA lyk en die inhoud van die pakkie
Wit, sirkelvormige, bikonvekse tablet en sonder onreëlmatighede, 9 mm.
MODAFINIL IPHARMA-tablette word verpak in hitte-verseëlde PVC-aluminium stulpstroke.
Stulpstroke van MODAFINIL IPHARMA-tablette word saam met die pamflette in kartonhouers met 30 tablette verpak.

Houer van die registrasiesertifikaat
iPharma (Edms) Bpk
Elevationlaan 124, Randjesfontein
Midrand, 1683, Suid-Afrika
Tel.no: 011 314 2366

Hierdie blad is laas hersien op
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