PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ANTABUSE®, 400 mg dispergettes

Disulfiram

ANTABUSE contains 13,14 mg sodium per dispergette

Sugar free

Read all of this leaflet carefully before you start taking ANTABUSE:

- 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.
- **ANTABUSE** 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 ANTABUSE is and what it is used for

2. What you need to know before you take ANTABUSE

3. How to take ANTABUSE

4. Possible side effects

5. How to store ANTABUSE

6. Contents of the pack and other information

1. WHAT ANTABUSE IS AND WHAT IT IS USED FOR:

ANTABUSE is used as a supportive medicine in the treatment of alcoholism. It contains the active ingredient, disulfiram. When you drink alcohol it is changed in the body into acetaldehyde, disulfiram blocks the enzyme which breaks down acetaldehyde. This leads to an increased level of acetaldehyde in the blood causing unpleasant physical reactions.

ANTABUSE is used in the treatment of people with drinking problems. If you are treated with **ANTABUSE**

and drink alcohol you will experience unpleasant physical reactions, which may stop you from drinking further alcohol.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ANTABUSE:

Do not take ANTABUSE:

- if you are hypersensitive to disulfiram or any of the other ingredients of ANTABUSE (listed in **section 6**)
- if you are hypersensitive to thiuram compounds, such as those used in rubber compounds, pesticides (any substance used to kill, repel, or control certain forms of plant or animal life that are considered to be pests) or fungicides (any toxic substance used to kill or inhibit the growth of fungi), isoniazid (an antituberculosis medicine) and metronidazole (an antibiotic)
- if you have recently consumed alcohol
- if you have severe heart disease or heart failure
- if you have high blood pressure
- if you have had a stroke
- if you are pregnant
- loss of control of reality
- if you have severe psychiatric or personality disorder
- if you have suicidal thoughts
- if you are using a medicine for nausea such as chlorpromazine
- if you have brain damage.

Warnings and precautions:

Take special care with ANTABUSE:

Before treatment with **ANTABUSE**, tell your doctor if you suffer from

- kidney, liver or lung disease
- diabetes
- low blood pressure
- brain damage
- epilepsy
- severe personality disorders and drug addiction

- suicidal thoughts
- nausea and using a medicine such as chlorpromazine to treat it
- heart disease.

Other precautions:

Certain foods, liquid medicines, remedies, tonics, toiletries, perfumes and sprays may contain enough alcohol to cause a disulfiram tablet -alcohol reaction. Caution should also be exercised with low alcohol and "non-alcoholic" or "alcohol-free" beers and wines. If enough is taken they may produce unpleasant reactions.

Children and adolescents:

Do not give **ANTABUSE** to children. There is no relevant use in children.

Other medicines and ANTABUSE

ANTABUSE may increase or decrease the effect of other medicines, if taken at the same time.

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

Please tell your doctor if you are taking or receiving any of the following medicines:

- amitriptyline (to treat depression)
- chlordiazepoxide and diazepam (to treat anxiety)
- pethidine and morphine (painkillers)
- amphetamines (stimulants)
- theophylline (to treat asthma)
- pimozide, and chlorpromazine (to treat mental illnesses)
- isoniazid metronidazole, rifampicin (to treat infections)
- phenytoin and paraldehyde (to treat epilepsy)
- warfarin (reduces blood clotting).

ANTABUSE and sodium:

This medicine contains less than 1 mmol sodium (23 mg) per dispergette, that is to say essentially "sodium-

free".

ANTABUSE with alcohol:

If you drink alcohol during or within 2 weeks of stopping **ANTABUSE**, or you have been exposed to alcohol from other sources (see '**Other precautions**') a disulfiram-alcohol reaction may occur. The reaction is unpredictable, and symptoms may be severe or life threatening (see **Warnings and precautions**). Symptoms include; flushing of the face and neck, increased body temperature, sweating, feeling or being sick, itchy skin or rash caused by an allergic reaction (pruritus, urticaria) anxiety, dizziness, headache, blurred vision, difficulty breathing, palpitations, rapid breathing.

In severe cases; rapid heartbeat, low blood pressure, abnormally slow breathing, chest pain, abnormal heart rhythm, coma or fits may occur.

Rare complications may include; high blood pressure, breathing problems, blood disorders.

If you get some of the symptoms, contact your doctor.

The disulfiram-alcohol reaction can occur within 15 minutes after drinking alcohol and may last several hours.

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 **ANTABUSE**.

You should not take **ANTABUSE** if you are pregnant or breastfeeding your baby.

Driving and using machines:

ANTABUSE may cause drowsiness or tiredness.

If you are affected do not drive or operate machinery.

It is not always possible to predict to what extent **ANTABUSE** 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 **ANTABUSE** affects you.

3. HOW TO TAKE ANTABUSE:

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

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

The usual dose is ½ to 1 dispergette daily or one dispergette every two days instead of half dispergette daily.

Your doctor will tell you how to take **ANTABUSE** and how long your treatment with **ANTABUSE** will last.

If you have the impression that the effect of **ANTABUSE** is too strong or too weak, tell your doctor or pharmacist.

Drop the whole or part dispergette into a quarter glass of water or other liquid.

It will effervesce at once and, after stirring for a few seconds, will form a palatable suspension.

Drink the suspension before it has had time to settle. Alternatively, **ANTABUSE** can be swallowed without chewing as normal tablets.

If you take more ANTABUSE than you should:

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

Take this leaflet and the rest of the remaining **ANTABUSE** with you so the doctor will know what you have taken.

Signs of an overdose include; feeling or being sick, stomach pain, diarrhoea, drowsiness, mental disorders, tiredness, rapid heartbeat, rapid breathing, high body temperature, low blood pressure, loss of muscle control, high blood sugar, changes in the blood (as seen in blood tests). Severe cases may result in coma, fits or death.

If you forget to take ANTABUSE:

If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take **ANTABUSE** at the next regularly scheduled time.

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

If you stop taking ANTABUSE:

Speak to your doctor or pharmacist before stopping treatment with **ANTABUSE**.

4. POSSIBLE SIDE EFFECTS:

ANTABUSE can have side effects.

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

If any of the following happens, stop taking **ANTABUSE** 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 **ANTABUSE**. 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:

- allergic skin reactions such as itching and redness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with unknown frequency:

- loss of contact with reality
- depression, paranoia, schizophrenia, mania
- decreased sexual desire
- sleepiness, drowsiness and fatigue (especially at start of treatment)
- damage/inflammation of peripheral nerves (causing pain and loss of sensation in hands and feet)
- inflammation of the optic nerve
- encephalopathy (brain disease)
- headache, restlessness
- feeling or being sick
- bad taste in mouth

- body odour
- inflammation of the liver (hepatitis), damage to liver cells, liver failure
- bad breath
- elevated levels of acetone in blood, causing symptoms such as headache, irritability, bad breath (ketosis breath), sugar cravings.

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 **ANTABUSE**.

5. HOW TO STORE ANTABUSE:

Store all medicine out of reach of children.

Store at or below 25 ºC, in a well closed container and protect from light.

Do not use the dispergettes 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 ANTABUSE contains:

The active ingredient is disulfiram.

The other ingredients are magnesium stearate, maize starch, microcrystalline cellulose, polysorbate 20, povidone, silica (colloidal anhydrous), sodium hydrogen carbonate, talc and tartaric acid.

What ANTABUSE looks like and contents of the pack:

ANTABUSE dispergettes are white, round, flat tablets with a 15 mm diameter, cross scored on one side and marked "CJ".

They are effervescent in water and form a palatable drink.

ANTABUSE is packaged in amber glass bottles or white HDPE bottles of 50 and amber HDPE bottles of 500 dispergettes.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: +27 11 055 0200

This leaflet was last revised in:

28 May 2021

REGISTRATION NUMBER(S):

G2932 (Act 101/1965)

PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS: **S3**

ANTABUSE®, 400 mg dispergette

Disulfiraam

ANTABUSE bevat 13,14 mg natrium per disperget

Suikervry

Lees hierdie hele blad noukeurig deur voordat u begin om ANTABUSE 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.
- **ANTABUSE 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 ANTABUSE is en waarvoor dit gebruik word

2. Wat u moet weet voordat u ANTABUSE drink

3. Hoe om ANTABUSE te drink

4. Moontlike newe-effekte

5. Hoe om ANTABUSE te bêre

6. Inhoud van die pak en ander inligting

1. WAT ANTABUSE IS EN WAARVOOR DIT GEBRUIK WORD:

ANTABUSE word gebruik as ondersteunende medisyne vir die behandeling van alkoholisme. Dit bevat die aktiewe bestanddeel disulfiraam. As u alkohol drink word dit in die liggaam na asetaldehied verander

en disulfiraam blokkeer die ensiem wat asetaldehied afbreek. Dit lei tot ’n hoë vlak van asetaldehied in die bloed wat onaangename fisiese reaksies veroorsaak.

ANTABUSE word gebruik vir die behandeling van mense met drankprobleme. As u met **ANTABUSE** behandel word en alkohol drink, sal u onaangename fisiese reaksies ervaar, wat u kan verhinder om verder alkohol te drink.

2. WAT U MOET WEET VOORDAT U ANTABUSE DRINK:

Moenie ANTABUSE drink nie:

- as u hipersensitief (allergies) vir disulfiraam of vir enige van die ander bestanddele van **ANTABUSE** (gelys in **afdeling 6**) is.
- as u hipersensitief vir tiuraamverbindings is, soos dié wat gebruik word in rubberverbindings, plaagdoders (enige stof wat gebruik word om sekere vorms van plante of diere wat as plae beskou word, dood te maak, af te weer of te beheer) of swamdoders (enige giftige stof wat gebruik word om swamme dood te maak of die groei daarvan rem), isoniasied (’n middel teen tuberkulose) en metronidasool (’n antibiotikum)
- as u onlangs alkohol gebruik het
- as u erge hartsiekte of hartversaking het
- as u hoë bloeddruk het
- as u ’n beroerte gehad het
- as u swanger is
- verlies aan beheer oor die werklikheid
- as u ’n erge psigiatriese of persoonlikheidsversteuring het
- as u selfdoodgedagtes het
- as u medisyne vir naarheid soos chloorpromasien gebruik
- as u breinskade het.

Waarskuwings en voorsorgmaatreëls:

Wees veral versigtig met ANTABUSE:

Sê voor behandeling met **ANTABUSE** vir u dokter as u aan die volgende ly:

- nier-, lewer- of longsiekte

- diabetes
- lae bloeddruk
- breinskade
- epilepsie
- ernstige persoonlikheidsversteurings en dwelmverslawing
- selfdoodgedagtes
- naarheid en die gebruik van medisyne soos chloorpromasien om dit te behandel
- hartsiekte.

Ander voorsorgmaatreëls:

Sekere voedsel, vloeibare medisyne, middels, tonika, toiletware, parfuum en bespuitings kan genoeg alkohol bevat om ’n disulfiraam-alkoholreaksie te veroorsaak. Wees ook versigtig met lae-alkohol- en nie-alkoholiese of alkoholvrye biere en wyne.
As genoeg daarvan gedrink word, kan dit onaangename reaksies veroorsaak.

Kinders en adolessente:

Moenie **ANTABUSE** vir kinders gee nie. Daar is geen toepaslike gebruik vir kinders nie.

Ander medisyne en ANTABUSE:

ANTABUSE kan die effek van ander medisyne verhoog of verlaag as dit terselfdertyd gebruik word.

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

Sê vir u dokter as u enige van die volgende middels gebruik:

- amitriptilien (vir depressie)
- chloordiasepoksied en diasepaam (om angs te behandel)
- petidien en morfien (pynstillers)
- amfetamiene (stimulante)
- teofillien (om asma te behandel)
- pimosied en chloorpromasien (vir geestesiektes)

- isoniasied, metronidasool, rifampisien (vir die behandeling van infeksies)
- fenitoïen en fenobarbitoon (vir epilepsie)
- warfarien (om bloedstolling te verminder).

ANTABUSE met alkohol:

As u alkohol saam met **ANTABUSE** drink of binne 2 weke nadat u dit gestaak het, of as u aan alkohol uit ander bronne blootgestel is (sien **Ander voorsorgmaatreëls**), kan ’n disulfiraam-alkoholreaksie voorkom. Die reaksie is onvoorspelbaar, en die simptome kan erg of lewensgevaarlik wees (sien **Waarskuwings en voorsorgmaatreëls)**. Simptome is onder meer gloede in die gesig en nek, hoë liggaamstemperatuur, sweet, ’n siek gevoel, jeukerige vel of uitslag as gevolg van ’n allergiese reaksie (pruritus, urtikarie) angs, duiseligheid, hoofpyn, dowwe visie, asemhalingsprobleme, hartkloppings, vinnige asemhaling.

In erge gevalle kan vinnige hartklop, lae bloeddruk, abnormale stadige asemhaling, pyn op die bors, abnormale hartritme, koma of aanvalle voorkom.

Skaars komplikasies kan hoë bloeddruk, asemhalingsprobleme en bloedafwykings insluit.

As u van hierdie simptome ervaar, moet u u dokter skakel.

Die disulfiraam-alkoholreaksie kan voorkom binne 15 minute na die drink van alkohol en dit kan ’n paar uur duur.

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 **ANTABUSE** drink.

U moet **ANTABUSE** nie drink as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjinerie:

ANTABUSE kan slaperigheid of moegheid veroorsaak.

As u aangetas word, moet u nie ’n voertuig bestuur of masjinerie hanteer nie.

Dit is nie altyd moontlik om te voorspel tot watter mate **ANTABUSE** met u daaglikse aktiwiteite kan inmeng nie. U moet sorg dat u nie ’n voertuig bestuur of masjiene hanteer nie, totdat u weet hoe **ANTABUSE** u beïnvloed.

3. HOE OM ANTABUSE TE DRINK:

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Drink **ANTABUSE** 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 is ½ tot 1 disperget daagliks of een disperget elke twee dae in plaas van ’n halwe disperget elke dag.

U dokter sal vir u sê hoe u **ANTABUSE** moet drink en hoe lank u behandeling met **ANTABUSE** sal duur.

Sê vir u dokter of apteker as u die indruk het dat die effek van **ANTABUSE** te sterk of te swak is.

Gooi die hele disperget of ’n gedeelte daarvan in ’n kwart glas water of ander vloeistof.

Dit sal dadelik bruis en sal ’n smaaklike suspensie vorm nadat dit vir ’n paar sekondes geroer is.

Drink die suspensie voordat dit neerslaan. Alternatiewelik kan **ANTABUSE** ingesluk word sonder om as normale tablette te kou.

As u meer ANTABUSE 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.

Neem hierdie blad en alle oorblywende **ANTABUSE** saam sodat die dokter kan sien wat u gedrink het.

Tekens van ’n oordosis is onder meer naarheid of braking, maagpyn, diarree, slaperigheid, geestesversteurings, moegheid, vinnige hartklop, vinnige asemhaling, hoë liggaamstemperatuur, lae bloeddruk, verlies aan spierbeheer, hoë bloedsuikervlakke, veranderinge in die bloed (soos in bloedtoetse gesien). Erge gevalle kan tot koma, aanvalle of sterftes lei.

As u vergeet om ANTABUSE te drink:

As u ’n dosis oorgeslaan het, gebruik dit sodra u onthou. As dit bykans tyd vir u volgende dosis is, los die oorgeslane dosis en drink **ANTABUSE** op die volgende gewone geskeduleerde tyd.

Moenie ’n dubbele dosis gebruik om vir vergete individuele dosisse op te maak nie.

As u ophou om ANTABUSE te drink:

Praat met u dokter of apteker voordat u behandeling met **ANTABUSE** stop.

4. MOONTLIKE NEWE-EFFEKTE:

ANTABUSE kan newe-effekte veroorsaak.

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

Indien enige van die volgende voorkom, moet u ophou om **ANTABUSE** te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling 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 **ANTABUSE** 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:

- allergiese velreaksies soos jeuk en rooiheid.

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:

Newe-effekte met onbekende frekwensie:

- verlies aan kontak met die werklikheid
- depressie, paranoia, skisofrenie, manie
- laer seksuele behoefte
- slaperigheid en moegheid (veral aan die begin van die behandeling)
- skade/ontsteking van perifere senuwees (veroorsaak pyn en verlies van gevoel in hande en voete)
- inflammasie van die optiese senuwee
- enkefalopatie (breinsiekte)
- hoofpyn, rusteloosheid

- naarheid of braking
- slegte smaak in die mond
- liggaamsreuk
- lewerontsteking (hepatitis), skade aan lewerselle, lewerversaking
- slegte asem
- hoë vlakke asetoon in bloed, wat simptome veroorsaak soos hoofpyn, geïrriteerdheid, slegte asem (ketose-asem), suikerdrang.

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 SAHPRA aanmeld *via* die vorm vir die aanmeld van nadelige geneesmiddelreaksies, naamlik **6.04 Adverse Drug Reaction Reporting Form** wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **ANTABUSE** te gee.

5. HOE OM ANTABUSE TE BÊRE:

Hou alle medisyne buite bereik van kinders.

Bêre onder 25 °C in ’n diggeslote houer en beskerm teen lig.

Moenie die dispergette 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 ANTABUSE bevat:

Die aktiewe bestanddeel is disulfiraam.

Die ander bestanddele is magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, polisorbaat 20, povidoon, silika (kolloïdale watervry), natriumwaterstofkarbonaat, talk en wynsteensuur.

Hoe ANTABUSE lyk en die inhoud van die pak:

ANTABUSE-dispergette is wit, ronde, plat tablette met ’n deursnit van 15 mm, met ’n gekruisde breeklyn op die een kant en "CJ” gemerk.

Hulle bruis in water en vorm ’n smaaklike drankie.

ANTABUSE is verpak in amberglasbottels of wit HDPE-bottels met 50 en amber HDPE-bottels met 500 dispergette.

Houer van die registrasiesertifikaat:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Kantoorpark

Magwasingelwes

Waterfall City

Midrand

Gauteng

2090

Tel.: +27 11 055 0200

Hierdie blad is laas hersien op:

24 May 2022

REGISTRASIENOMMER(S):

G2932 (Wet 101/1965)