PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

HY-AN 0,03 mg tablets

Levonorgestrel

Contains sugar:

Active tablets:

Sucrose: 34,51 mg

Lactose monohydrate: 47,56 mg

Read all of this leaflet carefully before you start taking HY-AN

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

1. What HY-AN is and what it is used for

HY-AN is an oral contraceptive. The active ingredient is levonorgestrel, which is a type

progesterone. It works by thickening the fluid (mucus) at the neck of the womb (cervix) making it very difficult for the sperm to reach the egg, and it also alters the lining of the womb to make it less likely to accept a fertilised egg.

2. What you need to know before you take HY-AN

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of HY-AN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Ensure that you do not suffer from the conditions listed below or that the prescribing doctor is aware that you may have had any of the listed conditions.

- undiagnosed vaginal bleeding,
- possible pregnancy
- severe arterial disease
- hormone dependent neoplasm
- severe liver disease such as hepatic adenoma
- porphyria

They should not be used after the recent evacuation of a hydatidiform mole.

Please inform the physician or dentist in charge that you are taking this medicine before any kind of surgery (including dental surgery) or emergency treatment. Your doctor will decide whether you should continue taking this medicine.

Do not take HY-AN

- If you have hypersensitivity to **HY-AN** or to any components of the formulation
- If you have liver disease or markedly impaired liver function
- If you suffer from hormone-dependent neoplasms, known or suspected
- Cerebrovascular disease or thromboembolic disease, active or past history thereof
- Undiagnosed genital bleeding

- Pregnancy
- If you have depression, which is not well controlled with treatment
- If you have had depression with previous use of hormonal contraceptives

Warnings and precautions

Take special care with HY-AN:

This contraceptive should be used with care in woman with

- heart disease
- malabsorption syndromes
- liver dysfunction, including recurrent cholestatic jaundice
- a history of jaundice in pregnancy
- functional ovarian cysts
- past ectopic pregnancy
- igraine (if focal)
- Hypertension
- Diabetes mellitus
- And thrombo-embolic disorders

Tell your doctor before using HY-AN:

- That you are on treatment for depression
- That you have had depression with previous use of hormonal contraceptives
- That you have a substance abuse problem
- You have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder
- That you have a family history of mental disorders
- That you have a history of physical or sexual abuse

Hormonal contraceptives including HY-AN, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression contact your doctor for advice.

Please note that

- Oral contraceptives may be used by women over the age of 35 years provided they do not smoke & have no other risk factors for cardiovascular disease. Oral contraceptive should be avoided over age of 50 years.
- The Use of oral contraceptives should be stopped 4 to 6 weeks before major elective surgery.
- The use of oral contraceptives may influence the results of certain laboratory tests including liver, thyroid adrenal, and renal function test, plasma concentrations of binding proteins and lipid/lipoprotein fractions and fibrinolysis and coagulation parameters.

Other medicines and HY-AN

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

Ensure that you take additional precaution not to fall pregnant while using the following medicines – **Antibacterials** (use additional method of contraceptives for an at least 7 days), antiepileptics, griseofulvin, and rifamycin antibacterials, and has also been suggested for some antivirals and for modafinil as they may cause failure of the oral contraceptives.

Antidepressants may cause adverse effects like intermenstrual bleeding and altered menstrual bleeding are reported in women on long term use of oral contraceptives.

Antidiabetics - Troglitazone may increase the clearance of oestrogen and progestogen. A high

dose of oral contraceptive or other method of contraception should be advised to women taking Troglitazone.

Antiepileptics - Oral contraceptive failure and breakthrough bleeding have been reported in women having antiepileptic therapy. Phenytoin, Phenobarbital, Primidone and Carbamazepine have been most frequently implicated, failure of OCP and oxcarbazepine, felbamate and topiramate may interact similarly with OCP.

Antifungals - Menstrual irregularities and pregnancies have been reported in women receiving oral contraceptive and griseofulvin.

Antivirals - Antivirals may decrease the efficacy of hormonal contraceptives as they accelerate the metabolism of oestrogen and progestogens.

Retinoids - Isotretinoin and combined oral contraceptives can have adverse effects on plasma lipids, should be monitored during concurrent administration of retinoid and oral contraceptive therapy.

Stimulants - Modafinil induces hepatic enzymes and may reduce the efficacy of oral contraceptives.

Oral contraceptive may antagonise (minimise) the effect of analgesics, anticonvulsants, anticoagulants, antihypertensives, benzodiazepines, cyclosporins, clofibrate, corticosteroids, lidocaine, selegiline, levothyroxine and xanthines**.**

- Increased clearance of paracetamol and morphine
- Increased and decreased effects reported with the use of anticoagulants
- Reduced effectiveness but also increased toxicity reported with some antidepressants
- Antagonism of the effect of antidiabetics
- Increased or decreased clearance reported with benzodiazepines
- Increased toxicity reported with ciclosporin
- Increased clearance and antagonism of the effect of clofibrate
- Reduced clearance and enhanced effect of corticosteroids

- Decreased clearance of selegiline
- Reduced free fraction of thyroxine due to an increased binding globulin concentration
- Increased free fraction of lignocaine due to altered protein binding
- Decreased clearance of xanthines

HY-AN with food and drink

There are no known interactions between HY-AN and food or drinks.

Pregnancy and breastfeeding

Pregnancy

Do not take HY-AN during pregnancy.

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 health care provider for advice before taking this medicine.

Lactation

Progesterone only contraceptives does not affect lactation, but should not be given until 3 weeks after birth to avoid an increased risk of breakthrough bleeding.

Driving and using machines

Based on the side effect profile of HY-AN, no effect is expected on the ability to drive and use machines.

HY-AN contains sucrose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking HY-AN.

Patients with the rare hereditary condition of lactose, fructose or galactose intolerance should not take HY-AN.

HY-AN contains sucrose and lactose, which may have an effect on the control of your blood sugar

if you have diabetes mellitus.

3. How to take HY-AN

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

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

HY-AN (levonorgestrel) must be taken exactly as directed and at intervals not exceeding 24 hours. Patients should be instructed to take the tablets at the same time every day, preferably after the evening meal or at bedtime.

The patient begins HY-AN (Levonorgestrel) on day 1 of her menstrual cycle, i.e. the first day of bleeding. One tablet is taken every day at the same time, without interruption, as long as contraception is desired. Tablets should be taken on this continuous daily regimen whether or not bleeding occurs. A mechanical method of contraception should be used until the first fourteen tablets have been taken.

If you take more HY-AN than you should

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

If you forget to take HY-AN

The risk of pregnancy increases with each tablet missed. If the patient misses one tablet she should be instructed to take it as soon as she remembers and to also take her next tablet at the regular time. If she misses two tablets, she should take one of the missed tablets as soon as she remembers as well as taking her regular tablet for that day at the proper time. In either case, she should use a mechanical method of contraception for the next 7 days. If she has missed one or two tablets and does not have a period within 45 days of her last, she should discontinue HYAN (levonorgestrel) and depend upon a mechanical method of contraception until the possibility of pregnancy has been excluded. If more than two tablets have been missed, HYAN (levonorgestrel)

should be discontinued immediately and a mechanical method of contraception should be used until menses has appeared or the possibility of pregnancy has been excluded. Alternatively, if the patient has taken the tablets correctly and if menses does not appear within 60 days from the last period, a mechanical method of contraception should be substituted until an appropriate diagnostic procedure is performed to exclude the possibility of pregnancy.

The contraceptive effectiveness may be reduced during episodes of vomiting or diarrhoea & extra contraceptive measures may be necessary during and for 7 days after recovery.

4. Possible side effects

HY-AN can have side effects.

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

If any of the following happens, stop taking / using HY-AN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden severe chest pain, sudden breathlessness, or severe pain /swelling in calf of one leg (possibly indicative of thromboembolic complications)
- Unusual, severe prolonged headache, sudden disturbances of vision or hearing or other perceptual disorders, collapse, marked numbness or weakness affecting one side of the body or other signs or symptoms suggestive of cerebrovascular accident.
- A first unexplained epileptic seizure.
- Hepatitis, jaundice, generalised itching, liver enlargement, severe upper abdominal pain.
- Significant rise in BP (above 160 mm Hg systolic or 100 mm/Hg diastolic)

These are all very serious side effects. If you have them, you may have had a serious reaction to HY-AN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Hyperglycaemia, weight gain
- Mood changes
- Headache, fatigue
- Fluid retention
- Abdominal pain or cramping, diarrhoea, nausea
- Amenorrhoea, breakthrough bleeding, menorrhagia, spotting

Less frequent side effects:

- Thromboembolism or thrombus formation
- Increases in hepatic enzyme levels, jaundice
- Melasma, acne, skin rash
- Breast pain or tenderness

Post marketing reported side effects:

- Suicidal thoughts/behaviour and suicide

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

5. How to store HY-AN

- Store at or below 25 ˚C. Protect from light.
- **Store all medicines out of reach of children**
- Do not store medicines in the bathroom in hot and moist conditions.
- Do not use the medicine after the expiry date on the container.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or

sewerage system (e.g. toilet).

6. Contents of the pack and other information

What HY-AN contains

- The active substance is levonorgestrel 0,03 mg
- The other ingredients are: Acacia, disodium edetate, ethyl cellulose, lactose monohydrate, magnesium stearate, maize starch, methyl hydroxybenzoate, microcrystalline cellulose, polacrilin potassium, polyethylene glycol, purified talc, sucrose, titanium dioxide (CI no. 77891).

What HY-AN looks like and contents of the pack

28 white sugar-coated tablets.

Aluminium/PVdC/PVC foil blister packs of 28 tablets (21 white and 7 red tablets) packed in a cardboard carton together with a leaflet.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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1601

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