

Regulator

Pharmaceutical Dosage Form: Sugar Coated Tablets.

Chemical Composition/Doses:

The active substances are: micronized oestradiol valerate and micronized cyproterone acetate. The other ingredients are: lactose corn starch, povidone, talc, magnesium stearate, saccharose, macrogol 6000, calcium carbonate, wax E, glycerol, titanium dioxide, yellow iron oxide, red iron oxide pigment.

Pharmacological classification: Hormones(oestrogens and Progestagens)

1-What is Regulator and in what situation is it used?

Progestagens and oestrogens in a fixed associations. ATC code: (G03FA)Urogenital system and sex hormones). This medicine contains a fixed ,sequential association of an oestrogen micronized oestradiol valerate) and a progestagen (micronized cyproterone acetate). The medicine is recognized for use in the treatment of problems due to oestrogen deficiency, particularly those associated with natural or artificial menopause (hot flushes, excessive sweating, urinary problems ,vaginal dryness, etc.) and to prevent post-menopausal osteoporosis.

2-Information required before using Regulator

Regulator must not be used in the following situations:
-active arterial or venous thrombo-embolic disease (inflammation of a vein with clot formation, blockage of a pulmonary blood vessel, myocardial infarction ,cerebrovascular accident due to blood clot)
- past history of venous thrombo-embolic disease .
- certain malignant tumours of the breast and uterus.
- vaginal bleeding of undiagnosed cause.
- certain liver disorders.
- known allergy to any of the ingredients in the product.
- pregnancy or breast feeding.

Regulator should generally not be used in the following situations.

Except on your doctor's advice: in certain cardiac disorders .

Warning and precautions for use for Regulator

Warning: this medicine is not a contraceptive . Report symptoms which persist despite treatment to your doctor .some women will undergo regular breast examinations (particularly those with a known breast cyst or nodule) . in certain patients , administrations of oestrogen-progestagens may lead to changes in the uterus (endometrium).

Regular gynaecological examinations must be performed by your doctor, you should consult your doctor if you suffer from heavy bleeding, because of the presence of lactose in the preparations, inform your doctor if you are suffering from congenital galactosaemia, glucose-galactose malabsorption syndrome or lactose deficiency, because of the presence of saccharose in the preparation, inform your doctor if you are suffering from fructose intolerance, glucose-galactose malabsorption syndrome or sucrose - isomaltase deficiency.

Precaution for use for Regulator

A medical examination is required before and intermittently during treatment. Report any previous disorders or disorders which occur during treatment to your doctor particularly:
- if you have suffered from a cerebrovascular accident (due to a haemorrhage or blood clot).
- if you have suffered from vascular problems (particularly problems in the retina of the eye).
- if you have suffered from itching during a previous pregnancy.
- or if there is past history of breast cancer in your family.

Treatment for the menopause is not contraindicated in all of these situations ,but does require special monitoring.

Particularly careful medical supervision is required if you are suffering from overweight, severe diabetes ,hypertension, increased triglycerides, endometriosis (a disorder characterized by the presence of uterine mucosa outside of the uterus) , renal insufficiency ,liver disorders, gallstones, epilepsy ,asthma, lupus (a severe disorder, Particularly affecting the skin)a pituitary tumour (a gland in the brain), porphyria (a hereditary disease), otospongiosis (a disorder of the ear ,causing reduced hearing).

Inform your doctor if you need to remain in bed or if you need to undergo a surgical procedure.

Pregnancy:

This medicine is not indicated during pregnancy or when breast-feeding. If this preparation is taken accidentally during pregnancy or when breast-feeding: stop treatment and Inform your doctor.

Important information relating to certain of the ingredients in Regulator (excipients with known effects).

Lactose ,saccharose.

Use of other medicines at the same time as Regulator

In order to avoid possible interaction between multiple medicines, Particularly with the anti-convulsant (Carbamazepine, Phenoobarbital, phenytoin, primidone), barbiturates, griseofulvin, rifabutin and rifampicin. You should always report any other treatment you are taking to your doctor or pharmacist.

3. How do I use Regulator ?

Dosage:

For oral use

Treatment consists of one tablet per day taken without interruption for 21 days, in the following order: 11 white tablets and 10 pink tablets followed by a treatment free period of 7 days. Treatment may be started on any day.

However, if you are changing from sequential replacement hormone therapy to **Regulator**, it is recommended that treatment is started after your period i.e. the day on which the next cycle of your sequential hormone therapy is due to start. A withdrawal bleed (period) may occur during the treatment free period.

This bleeding is normal and is not heavy.

Consult your doctor if heavy or irregular bleeding develops.

Tablets should be taken in the following order: 11 white tablets followed by 10 pink tablets. Carefully detach the calendar disc. Stick it onto the being coloured disc on the tablet sheet and set the day when you take the first tablet exactly underneath the being "start" box. For example, if the first tablet is taken on a Monday, you should stick the calendar disc onto the tablet sheet so that the "MON" is located underneath the being, "start" box. This will enable you to check that you are taking your **Regulator** regularly.

Day 1

Start the tablet sheet with the white tablet in the " start" box.

On subsequent days: Follow the order shown by the arrows.

Subsequent tablet sheets

You should start your sheet after a treatment free period of 7 days, excluding the day of your period, if this occurs.

If, for example, you started the first tablet sheet on a Monday, you should start the following sheets on Monday, even if your period has not finished.

Always follow your prescription carefully.

Frequency of administration: See Dosage section.

Duration of treatment: See Dosage section.

If you have taken more than one tablet of Regulator per day:

The effects caused by overdose generally consist of painful breasts, swollen stomach, irritability and anxiety.

No specific treatment is required: continue to take your **Regulator**, at a dose of one tablet per day.

If you suffer from these signs when you are taking one tablet of **Regulator** per day, consult your doctor.

If you forgotten to take one or more **Regulator** tablets:

If the delay in taking a tablet is less than 24hours, take the tablet as soon as possible.

If the delay is more than 24 hours, or if you have omitted several consecutive tablets, take the next tablet at the normal time.

If you have not taken your tablets for several consecutive days, you may develop irregular bleeding. Do not take a double dose to compensate for the single dose which have forgotten to take.

Effects which may develop when Regulator treatment is stopped

in all cases, carefully follow your doctor's prescription.

4. WHAT POSSIBLE SIDE EFFECTS ARE THERE?

As applies to all medicines, **Regulator** may cause side effects.

If you suffer from persistent hot flushes, headaches, uncomfortable vaginal dryness, irritation of the eyes due to contact lenses, nausea, vomiting, swollen breasts, irritability or feelings of heaviness in your legs, ask your doctor's advice, your doctor may adjust your treatment.

If you suffer from vaginal bleeding outside of the time when you are not taking treatment, consult your doctor.

Please inform your doctor or pharmacist, if you suffer, from any adverse effect not listed in this leaflet.

5. HOW SHOULD CLIMEN BE STORED ?

Keep out of reach of children.

Do not use after the expiry date shown on the pack.

Do not use **Regulator** if you see any visible signs of deterioration.

Return the medicine to your pharmacist.

Produced by: **IDM** International Drug - Manufacturing - Syria - Aleppo

Lic.No: 116 / 2011

THIS IS A MEDICAMENTS

A medicament is a product but unlike any products.

A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medicament.

The doctor and the pharmacist are experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed.

Do not repeat the same prescription without consulting your doctor.

COUNCIL OF ARAB HEALTHMINISTERS

KEEP MEDICAMENTS OUT OF REACH OF CHILDREN

ARAB PHARMACISTS ASSOCIATION

