

Package leaflet: Information for the user

Bella HEXAL® 35

2 mg/0.035 mg coated tablets

Active substances: Cyproterone acetate/Ethinylestradiol

Read the entire package leaflet carefully before you start taking this medicine.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if they have the same symptoms as you.
- If any of the side effects gets serious, or if you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

This package leaflet contains:

1. What are Bella HEXAL® 35 tablets and what are they used for?
2. What do you need to know before taking Bella HEXAL® 35 tablets?
3. How to take Bella HEXAL® 35 tablets?
4. What side effects are possible?
5. How to store Bella HEXAL® 35 tablets?
6. Further information

1. What are Bella HEXAL® 35 tablets and
What are they used for?

Bella HEXAL® 35 is used for the treatment of women
with

- severe acne that does not improve after continuous use of antibiotics
- excessive hair growth on the face and body

Cyproterone acetate blocks the effects of male hormones present in women on the skin. It can suppress the activity of the sebaceous glands and reduce the infections and inflammations that cause acne pimples.

Additionally, this medication reduces hair growth caused by too many male hormones.

The contraceptive effect

Bella HEXAL® 35 is also an effective contraceptive, so no other contraceptive pills need to be taken.

However, this medication should not be used solely for contraception.

Bella HEXAL® 35 is a combination of the two female hormones

estrogen and progestogen.

Estrogen and progestogen.

2. What you need to know before taking Bella HEXAL® 35 tablets?

Do not take Bella HEXAL® 35 or stop the treatment immediately if you:

- are hypersensitive (allergic) to cyproterone acetate, ethinylestradiol or any of the other ingredients of Bella HEXAL® 35
- are pregnant or think you might be pregnant
- are breastfeeding
- or your biological parents, brothers, and sisters have or ever had:
 - blood clots
 - a heart attack
 - a stroke or
 - any condition that increases your risk of developing blood clots
- have sickle cell anemia
- have abnormal blood lipid levels
- have or are suspected to have cancer of the breast or the endometrium or have ever had such cancer
- have unexplained vaginal bleeding
- unexplained bleeding from your vagina have
- suffer from certain forms of jaundice (Dubin-Johnson or Rotor syndrome)
- have severe diabetes with changes in the blood vessels

- have or have ever had liver tumors
- suffer from any type of liver disease
- have severe high blood pressure
- suffer from a certain type of migraine where you see bright spots
- had any of the following conditions during pregnancy:
 - itching all over the body had
 - worsening of hereditary deafness
 - jaundice.

Inform your doctor if any of the above applies to you.

- Jaundice.

- first occurrence of a migraine or more frequent migraine attacks than Applies to you.

Stop taking Bella HEXAL® 35 and seek imme-

Contact your doctor if you experience any of the following complaints the comes:

- first occurrence of a migraine or more frequent migraine attacks than common
- unusually severe headaches or more frequent headaches headaches
- sudden changes in vision, hearing, speech, smell, taste, or touch
- dizziness or fainting
- signs of blood clot formation or vein inflammation, such as
 - unusual pain or swelling in your legs or

arms

- stabbing pain in your chest
- sudden shortness of breath
- crushing pain or tightness in your chest
- cough without an obvious reason
- sudden weakness or numbness on one side of your body
- yellowing of the skin or itching all over the body
- increase in epileptic seizures
- significant increase in blood pressure
- severe depression
- severe upper abdominal pain or unusual swelling of the

Abdomen

- any worsening of diseases or complaints compared to previous events during pregnancy or the use of the pill

Use of the pill

This medicine must be discontinued six weeks before a planned major surgery, such as abdominal or leg surgery, or

medical treatment of varicose veins.

You must also stop taking the tablets if you are unable to move for several weeks, for example, due to a plaster cast. Your doctor will tell you when you can resume taking the tablets.

Be sure to read the information at the end of section 3 of this package leaflet if you need to stop taking Bella HEXAL® 35.

Special caution is required when taking Bella HEXAL® 35

Before you start taking this medicine, your doctor will

examine the following:

package leaflet if you are taking Bella HEXAL® 35 must be discontinued.

Special precautions when taking Bella HEXAL® 35 is required

Before you start taking this medication, your doctor will

Examine the following:

- Your medical history and also that of your family members
- Your blood pressure
- Your breasts as well as your abdominal and pelvic organs
- Whether you are pregnant or not and
- He will take a smear from your cervix.

Inform your doctor before starting treatment if:

- You suffer from depression or have suffered from it in the past
- You are over 30 years old and smoke
- You have been in the last six weeks
- Limited in your mobility

- Had major surgery such as leg surgery
- Suffered a major trauma such as shock or a life-threatening situation
- You have suffered from enlarged ovaries
- Anyone in your family has or had breast cancer
- You are over 40 years old.

Inform your doctor if during treatment you experience the following diseases or complaints

- Varicose veins
- Diabetes or a tendency to diabetes
- High blood pressure
- Epileptic seizures
- A form of hearing loss
- Multiple sclerosis, a disease of the nervous system
- A disease called porphyria, associated with the blood pigment Hemoglobin
- Calcium deficiency with cramps
- A movement disorder called Sydenham's chorea
- Breast complaints including cysts
- Heart and vascular diseases
- Kidney diseases
- Overweight
- An intolerance to contact lenses
- A disease called lupus erythematosus of the immune system, affecting skin and internal organs
- Asthma
- Benign tumors of the uterus or uterine lining
- A condition called endometriosis, where cells of the uterine lining are found outside the uterus
- Gallstones
- Migraine
- brown spots on the face and body
- any disease that can worsen during pregnancy, such as diabetes.

If any of these conditions or complaints worsen or occur for the first time, you must stop taking this medication.

Avoid ultraviolet lamps, tanning beds, or prolonged sunbathing while taking Bella HEXAL® 35, as this may promote possible patchy skin discoloration.

Additional special warnings

Blood clots

Parts of the following information actually concern the 'pill', but also apply to Bella HEXAL® 35.

Studies have shown that women who use medications like this have an increased risk of developing various circulatory disorders compared to women who do not use them. This can lead to the formation of blood clots known as thrombosis, which can block blood vessels. Most blood clots can be treated without long-term damage. However, they can also lead to permanent and in very rare cases lead to death.

Blood clots in the veins, such as those in the legs, can travel to the pulmonary vessels and block them there. Very rarely, blood clots can also occur in the blood vessels of the heart or brain, causing a heart attack or stroke. In extremely rare cases, blood clots can also occur in other places such as the liver, intestines, kidneys, or eyes.

The risk of developing blood clots is higher in users of a combination pill than in non-users. Some data suggest that the risk is higher in users of Bella HEXAL® 35 compared to users of other low-dose combination pills. However, the risk is lower than during pregnancy. A thrombosis is most likely to occur in the first year of using a combination pill. Among 100,000 healthy women who are neither pregnant nor using the 'pill',

there are about 5–10 cases of thrombosis each year. Among women using pills like Bella HEXAL® 35, up to 40 thromboses occur each year per 100,000 women. And among pregnant women, there are about 60 cases of thrombosis per 100,000.

The risk of thrombosis is increased under the following conditions:

Under the following conditions, the risk of thrombosis is increased:

- Age
The risk increases with advancing age.
- Smoking
Heavy smoking and increasing age further increase the risk. Stop smoking if you are using the pill, especially if you are older than 35 years.
- Overweight (Body Mass Index > 30 kg/m²)
- certain heart valve defects, heart rhythm disorders, and blood vessel diseases
- Diabetes
- Migraine
- after surgery or with less movement than usual
- existing or previous disease due to blood clots, such as thrombosis, heart attack, or stroke in your close relatives
- Varicose veins
- High blood pressure

- Lipid metabolism disorders and other blood diseases

The skin problems treated with Bella HEXAL® 35 may possibly also be caused by conditions that increase the risk of heart and vascular diseases.

The 'Pill' and Cancer

- Breast cancer

Breast cancer has been observed slightly more frequently in women who take a combination pill. However, it is not known whether there is a connection with the use of the pill.

For example, it may be that tumors are detected more frequently in women who take a combination pill

because these women are examined more often by their doctor.

After stopping the combination pill, the occurrence of breast cancer gradually decreases again.

It is important that you have your breasts examined regularly, and if you notice any lumps, you must definitely see your doctor.

- Other cancers

The use of the 'pill' can lead to the following:

- in rare cases, liver diseases such as jaundice and benign liver tumors

- very rarely malignant liver tumors with long-term use of the 'pill'.

Liver tumors can lead to life-threatening bleeding in the abdominal cavity
Pill.

Liver tumors can lead to life-threatening bleeding in the abdominal cavity and lead to severe pain in the upper abdomen. See also "Take Do not take Bella HEXAL® 35 ..." at the beginning of section 2.

In women who use the 'pill' long-term, some studies have reported an increased risk of cervical cancer. However, it is not certain whether this increased risk is due to the 'pill'.

Children

This medicine is not recommended for children.

Taking Bella HEXAL® 35 with other medicines

Please inform your doctor, dentist, or pharmacist if you are taking

or have recently taken/used other medicines, even if they are non-prescription medicines.

Medicines that can weaken the effects of Bella HEXAL® 35 are:

- Antibiotics such as ampicillin, rifampicin, doxycycline, tetracycline, minocycline

If you are taking an antibiotic to treat acne and Bella HEXAL® 35 cyclin

please inform your doctor.

Antibiotics applied to the skin do not restrict the contraceptive

effect.

- Griseofulvin, a medicine for treating fungal infections
- tende effect does not occur.
- Griseofulvin, a medication for the treatment of fungal infections
- Phenylbutazone, a medication for relieving pain or inflammations
- Phenytoin, primidone, phenobarbital, and some other medications for the treatment of epilepsy
- Barbiturates, sleeping pills, and sedatives
- Carbamazepine, a medication for the treatment of epilepsy or other conditions.

If you are using any of the above-mentioned medications, an additional contraceptive method such as condoms is required during treatment and for another 7 days after the end of treatment.

If your current pack runs out during these 7 days, start the next pack the next day without interruption.

If you use two cycle strips consecutively, you may not have a menstrual bleeding until the end of the second cycle strip. If you do not have a menstrual bleeding after taking the second cycle strip, please inform your doctor before starting the next pack.

If you take Bella HEXAL® 35 together with rifampicin, please use

another contraceptive method during and up to 4 weeks after stopping the treatment.

another contraceptive method.

- Other contraceptive pills

These 'pills' are not recommended if you are taking Bella HEXAL® 35. take.

- Medicines for the treatment of diabetes

Your doctor may change the dose of the medication required for the treatment of diabetes.

- Medicines containing St. John's Wort

Do not take any medications containing St. John's Wort while using Bella HEXAL® 35.

Pregnancy and breastfeeding

You must not take Bella HEXAL® 35 if you are pregnant or think you might be pregnant or while you are breastfeeding.

The use of this medicine can be particularly harmful to a male

unborn child, as it can prevent the development of the sexual
may be harmful to the unborn child as it affects the development of the sex-
Consult your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Seek advice.

use machines.

It is unlikely that Bella HEXAL® 35 affects the ability to drive and the ability to operate machinery is impaired.

Important information about certain other ingredients of Bella HEXAL® 35

This medicine contains sucrose and lactose. Please take Bella HEXAL® 35 only after consulting your doctor if you know that you suffer from an intolerance to certain sugars.

3. How should Bella HEXAL® 35 tablets be taken?

Always take Bella HEXAL® 35 exactly as your doctor has instructed. Please ask your doctor or pharmacist if you are not completely sure. Unless otherwise prescribed by the doctor, the usual dose is

1 tablet daily

Take the tablets daily at the same time, for example

after breakfast, unchewed with a glass of water.

Start taking Bella HEXAL® 35

Take the first Bella HEXAL® 35 tablet on the first day of your next menstrual period, i.e., when your bleeding starts. Women who do not have monthly bleeding, i.e., when your bleeding starts. Women who do not have a period should start treatment immediately if you no longer have your period. Also note the instructions for other users below. If your period starts on a Wednesday, for example, take a tablet marked with 'Wed'.

Follow the arrow along the marked weekdays until all 21 tablets are used up. Then do not take any tablets for 7 days. During this break, your period should start, usually 2 or 3 days after you have taken the last tablet. During the 7-day break, you will not become pregnant, provided you have taken the tablets correctly.

Start taking the tablets from the next cycle strip on day 8, even if your period has not yet stopped. Always start a new cycle strip on the same day of the week as the previous one.

Switching from another 'pill'

If you follow the instructions below, you will have immediate contraceptive

protection.

- '21-day pill'

Finish the old pack and start taking Bella HEXAL® 35 the next day without a break. Then please follow the instructions above under the heading "Start taking Bella HEXAL® 35" described instructions.

You may not have a menstrual period until the first cycle strip of Bella HEXAL® 35 is used up, but slight bleeding may occur while taking the tablets.

- '28-day pill'

Start Bella HEXAL® 35 immediately after taking the last active ingredient-containing tablet of the old 'pill'. If you are unsure which tablets contain the active ingredient, please ask your doctor or pharmacist.

Then please follow the instructions described above under the heading "Start taking Bella HEXAL® 35".

You may not have a menstrual period until the first cycle strip of Bella HEXAL® 35 is used up, but slight bleeding may occur while taking the tablets.

- Mini-pill (estrogen-free 'pill')

Take the first Bella HEXAL® 35 tablet on the first day of your menstrual period, even if you have already taken a mini-pill on that day. have taken.

taking Bella HEXAL® 35".

described instructions under "Taking Bella HEXAL® 35" and take only Bella HEXAL® 35.

If you start taking Bella HEXAL® 35 in this way, you have immediate contraceptive protection.

After the birth of a child

Your doctor will likely advise you to start taking Bella HEXAL® 35 21 days after birth. You do not need to wait for your menstrual period. Use an additional contraceptive method until the beginning and during the first 7 days of taking Bella HEXAL® 35. Then please follow the instructions described above under the heading "Starting to take Bella HEXAL® 35."

You must not breastfeed while taking Bella HEXAL® 35.

After a miscarriage or an abortion

In these cases, your doctor will likely advise you to start taking Bella HEXAL® 35 immediately. Then please follow the instructions described above under the heading "Starting to take Bella HEXAL® 35."

Duration of use

In general, treatment with Bella HEXAL® 35 is over several

Duration of use

In general, treatment with Bella HEXAL® 35 over several months required. If your skin is completely clear or the excessive hair growth on the face and body has decreased, the treatment should be continued for at least another 3 to 4 monthly cycles.

After that, however, you should not continue taking Bella HEXAL® 35 solely for contraception. If symptoms recur, you can repeat the treatment with Bella HEXAL® 35.

If the treatment success in severe acne after at least 6 months of treatment or in extreme hair growth after at least 12 months of treatment is not sufficient, your doctor will reconsider the treatment.

Absence of menstruation during the 7-day intake

If treatment for a month is not sufficient, your doctor will continue the treatment

In this case, regardless of whether you forgot to take the

tablets or not, you should immediately inform your doctor and not start the next cycle strip without his permission.

In the meantime, you must use other contraceptive methods, such as condoms or a diaphragm/cervical cap plus spermicide (sperm-killing agent).

Spotting

Some women may experience spotting while taking this medication of the drug).

Intermenstrual bleeding

In some women, during the use of this medication especially in the first months, breakthrough or spotting bleeding may occur. Normally, these stop again after one or two days.

Continue taking your tablets as usual and the problem should disappear on its own after the first few cycle strips.

However, if these bleedings keep recurring or last a long time or only occur for the first time after several months, please inform your doctor.

Unexpected bleeding can also be a sign of irregular tablet intake. Therefore, take the tablets at the same time every day.

If you have taken a larger amount of Bella HEXAL® 35

than you should

In this case, please inform your doctor. An overdose can cause nausea, vomiting, and withdrawal bleeding.

If you have forgotten to take Bella HEXAL® 35

- If you have forgotten one or more tablets
- If more than 12 hours have passed since the last due intake time or you have forgotten to take more than one tablet:

Use additional contraceptive methods, as the contraceptive

eaten:

Use additional contraceptive methods, as conception-protection may no longer be ensured.

Follow the instructions for the 7-day rule:

Take the last missed tablet and continue with taking your next tablets at the usual times, and

use an additional contraceptive method such as condoms for the next 7 days, and

if your current cycle strip ends before these 7 days, start the next strip the very next day.

Your menstrual bleeding will not occur in this case until this next cycle strip is used up. However, this is no cause for concern. You also need not worry if intermenstrual bleeding occurs while taking the tablets.

However, if no menstrual bleeding occurs during the subsequent 7-day break, please refer to the section "Absence of menstrual bleeding during the 7-day break."

- If taking a tablet is delayed by 12 hours or less:

If you take the missed tablet immediately, the contraceptive effect should

- If the intake of a tablet is delayed by 12 hours or less delayed:

If you take the missed tablet immediately, the emp-protection against pregnancy is not reduced. Then take your tablets again at the usual time.

• If a tablet is lost

Take the last tablet of the cycle strip instead of the lost tablet. Then continue taking all tablets on the scheduled days. This will make your monthly cycle one day shorter than usual, but it will not affect your contraceptive protection. After the 7 tablet-free days, start taking the tablets one day earlier than before. If you lose a started cycle strip, please ask your doctor or pharmacist what to do.

What to do in case of vomiting or severe diarrhea

If you have to vomit or experience severe diarrhea within 3–4 hours after taking your tablet, the effectiveness of the medication may be reduced. If this happens and you rely on the contraceptive protection of this medication:

- continue taking the tablets

and

- use an additional contraceptive method such as condoms for up to 7 days after recovering from your stomach upset.

If your cycle strip is finished before the seven days, start you continue immediately with the next cycle strip. In this

case, you may not have a menstrual period until the end of this second cycle strip. If no menstrual period occurs after the second cycle strip, you must inform your doctor before starting the next cycle strip.

If your stomach upset persists for a longer period, please consult your doctor, who may consider another type of contraception for you in this case.

If you want to have a baby

Stop taking Bella HEXAL® 35 and use another contraceptive method until you have a normal menstrual period again. However, there is no need to worry if you become pregnant immediately.

If you stop taking Bella HEXAL® 35

Always take this medicine regularly to avoid irregular menstrual periods and to prevent pregnancy.

If you stop the treatment and do not want to become pregnant, you must use another contraceptive method such as a condom.

After discontinuing Bella HEXAL® 35, irregular or missed menstrual periods, especially if this was the case for you even before starting the treatment. It may therefore take some time before you have regular menstrual periods again.

If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, Bella HEXAL® 35 can have side effects, which do not necessarily occur in everyone.

The side effects can occur with the following frequencies:

- Rare: occur in 1 to 10 users out of 10,000
- Not known: frequency cannot be estimated from the available data

Serious side effects

Rare cases

Rare cases

See section 2 "Other cancers"

Frequency not known

- Severe depression
- Severe depression

Although severe depression is not considered a direct side effect of Bella HEXAL® 35, you should discontinue treatment with Bella HEXAL® 35 as a precaution if severe depression occurs.

as a precautionary measure.

- Blood clots in a vessel of the leg, lung, heart, or brain
See section 2 "Stop taking Bella HEXAL® 35 ..."
and "Blood clots"

- a slightly increased risk of breast cancer
See section 2 "Bella HEXAL® 35 must not be taken ..."
and "Breast cancer"

If any of the above applies to you, stop taking this medication immediately and inform your doctor. Remember that you must use another method of contraception if you do not wish to become pregnant.

Other side effects

Side effects may occur more frequently in the first months after starting treatment.

Rare

- depressive moods
- headaches
- nausea, vomiting, and stomach upsets
- sore or enlarged breasts
- lack of sexual desire
- weight changes

Frequency not known

- increase in epileptic seizures
- hearing, vision, or sensory disturbances
- increase in blood pressure
- yellowish-brown spots on the skin (chloasma).

These can also occur after you have been taking Bella HEXAL® 35 for several months, and can be reduced by avoiding too much sun exposure. See section 2 "Inform

your doctor if you experience the following conditions or complaints during treatment"

- breakthrough or spotting between your menstrual periods during the first few months. These generally stop once your body has adjusted to the medication. See section 3 "Inter-menstrual bleeding"
- weakened menstrual bleeding
- missed menstrual period or irregular bleeding

See section 3 "Absence of menstrual bleeding during the 7-day

See section 3 "Absence of menstruation during the 7-day

Intake break

- poor tolerance of contact lenses

Withdrawal reactions

For effects that occur after stopping this medication, see section 3 "If you stop taking Bella HEXAL® 35 break"

Influence on blood test results

You must always inform your doctor or laboratory staff that you are taking Bella HEXAL® 35.

Please inform your doctor or pharmacist if you notice side effects.

5

5. stored?

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the carton and the cycle

strip after "use by". The expiry date refers to the last day of the month.

Storage

apply. The expiration date refers to the last day of the month.

Storage

Store in the original packaging.

The medicine must not be disposed of in wastewater or household waste.

Ask your pharmacist how to dispose of the medicine

if you no longer need it. This measure helps to protect the environment.

6

6. What Bella HEXAL® 35 contains

The active ingredients are: cyproterone acetate and ethinylestradiol.

Each tablet contains 2 mg cyproterone acetate and 0.035 mg ethinylestradiol.

The other ingredients are:

Tablet core: lactose monohydrate, corn starch, povidone K25, talc, magnesium stearate (Ph.Eur.)

Tablet coating: sucrose (sugar), calcium carbonate, polyethylene glycol 6000, povidone K90, titanium dioxide (E171), glycerol 85%, montanglycol wax, iron(III) hydroxide oxide (E172)

What Bella HEXAL® 35 looks like and contents of the pack

Bella HEXAL® 35 are round, biconvex, yellow, sugar-coated

tablets with a nominal diameter of 5.7 mm.

tablets with a nominal diameter of 5.7 mm.

The coated tablets are packed in plastic/aluminum blister strips,

each containing 21 coated tablets and are in an outer carton.
ton befinden.

Pharmaceutical company

HEXAL AG
Industriestraße 25
83607 Holzkirchen
Phone: (08024) 908-0
Fax: (08024) 908-1290
e-mail: service@hexal.com
Manufacturer

Salutas Pharma GmbH,
a company of HEXAL AG
Otto-von Guericke-Allee 1
39179 Barleben
39179 Barleben

Economic Area (EEA) under the following names:

United Kingdom: Hexal AG Cyproterone Acetate 2.00mg Ethinylestradiol

0.035mg Coated Tablets

0.035mg Coated Tablets

Germany: Bella HEXAL® 35 2 mg/0.035 mg coated tablets

Belgium: Claudia 35

This package leaflet was last approved in
December 2008.