

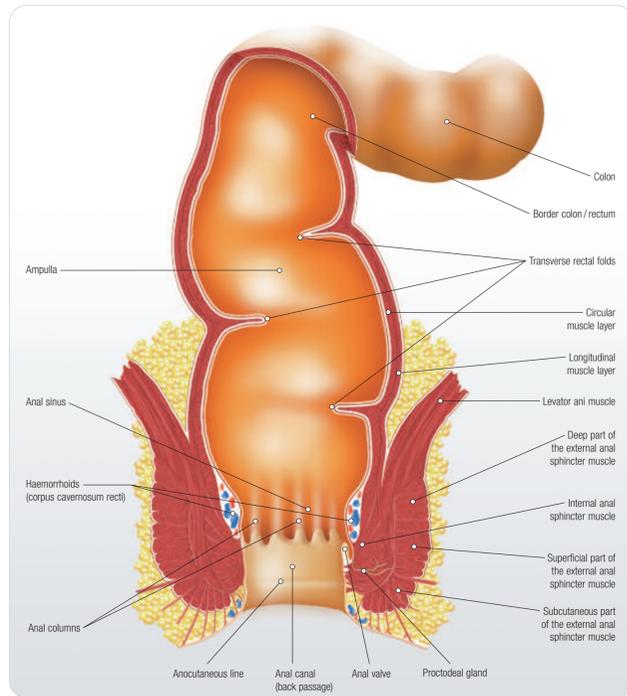


HAEMORRHOIDS – A COMMON DISEASE

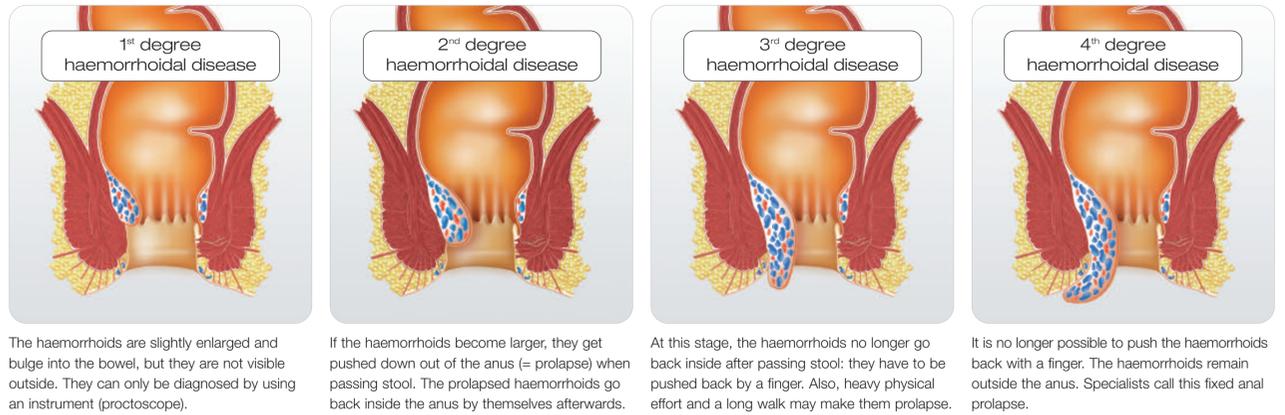
WHAT ARE HAEMORRHOIDS?

Where the rectum joins the anal canal (back passage), there are cushions of blood vessels that form a ring under the lining (mucosa) of the bowel. Everybody has these cushions and they have an important task – they are responsible for keeping the end of the bowel properly closed. We talk about haemorrhoids as a disease (haemorrhoidal disease, piles) if these blood vessel cushions become enlarged and thus cause symptoms.

ANATOMY OF THE RECTUM



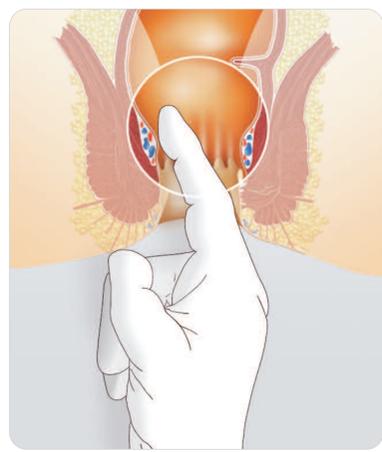
FOUR DEGREES OF THE CONDITION CAN BE DISTINGUISHED, DEPENDING ON SEVERITY:



WHAT ARE THE SYMPTOMS OF HAEMORRHOIDAL DISEASE?

- Bright red bleeding (drops of blood in the toilet bowl, coating of blood on the stools or on the toilet paper)
- Itching, burning, stabbing pains, wetness
- Inflamed skin around the anus (eczema)
- Foreign body sensation, feeling of incomplete emptying of the bowels
- Protrusion of the haemorrhoids from the anus (prolapse)
- Uncontrolled leakage of stool (faecal incontinence) in severe cases

HOW DOES THE DOCTOR DIAGNOSE HAEMORRHOIDAL DISEASE?



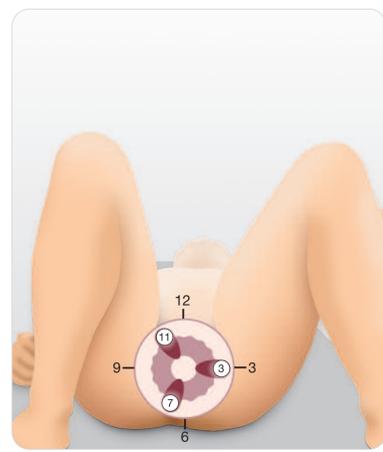
RECTAL EXAMINATION (PALPATION) WITH THE FINGER:

The doctor will insert a finger to palpate the rectum. In that way the doctor can feel any knobby changes or any narrowing and can check the tone of the muscles that close the anus. It is not usually possible to actually feel haemorrhoids, so it might then be necessary to look inside the back passage with an instrument.



PROCTOSCOPY / RECTOSCOPY:

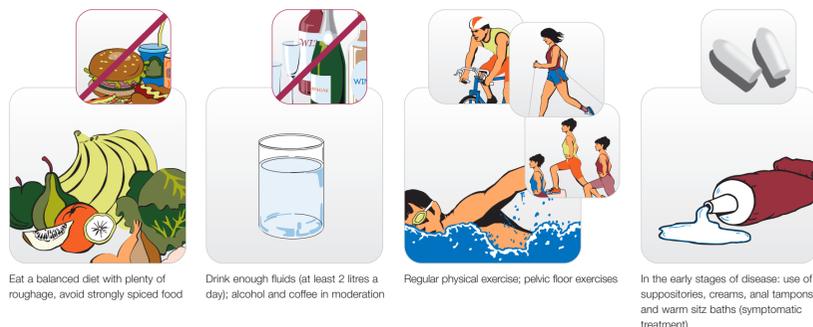
The examination of the anal canal and rectum is performed with special instruments (proctoscope or rectoscope). These are narrow, stiff tubes of different lengths that are carefully inserted into the anal canal or rectum. The doctor can then examine the inside of the last part of the intestine for any abnormalities and check whether you have haemorrhoids.



SITE:

Haemorrhoids are typically found at the 3 o'clock, 7 o'clock and 11 o'clock positions when the patient is in the lithotomy position on the examination table.

WHAT CAN YOU DO AGAINST HAEMORRHOIDAL DISEASE?



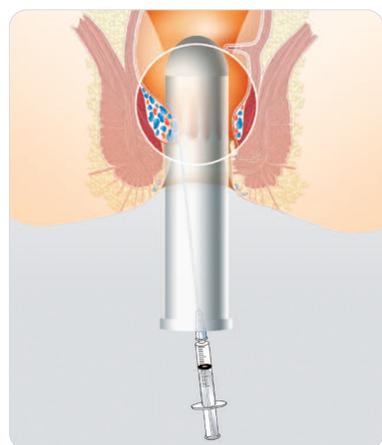
RISK FACTORS:

Haemorrhoids are caused or exacerbated by congenital weakness of connective tissue and various risk factors such as:



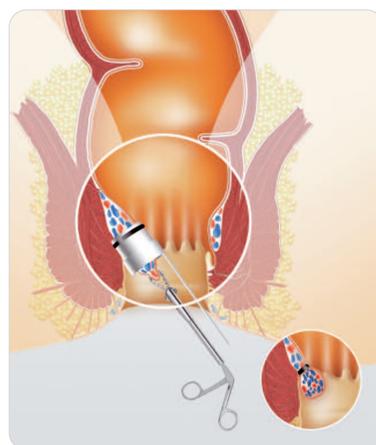
TREATMENT OF HAEMORRHOIDAL DISEASE

Commonly used methods of treatment for 1st and 2nd (3rd) degree haemorrhoidal disease:



SCLEROTHERAPY (OBLITERATION):

Sclerotherapy is a highly effective method that can be performed on an outpatient basis. Through the opening of a proctoscope the doctor injects a liquid "sclerosing" agent directly into the (submucosal) haemorrhoids or into the region around the supply vessels. This has the desired effect of causing a reaction in the tissues, the haemorrhoids shrink and become fixed to the underlying tissue. Treatment is easy and painless when performed expertly. That is because the human body has no pain nerves in the area where the injection is given and so you cannot feel anything.



BANDING (RUBBER BAND LIGATION):

Banding involves grasping the haemorrhoids with special forceps or a suction instrument and then binding them round with an elastic band. This shuts off the blood supply to the haemorrhoids and the sealed-off tissue dies. The dead tissue drops off after about four to ten days and is passed out with the stools.



OPERATION:

If you go to the doctor early enough, in most cases you can avoid an operation. In very advanced stages, however, the haemorrhoids have to be removed under anaesthetic by an operation.

Extract translated from the German SPC

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Anthoxyklon 3%
Active substance: lauracromogol 400 (polysaccharide)

Qualitative and quantitative composition
Anthoxyklon® is a sclerosant based on lauracromogol 400 and contains the following amounts of active substance: 2 ml Anthoxyklon 3% contain 60 mg lauracromogol 400 (polysaccharide).

Excipients
Ethanol 96 %, potassium dihydrogen phosphate,

dipotassium phosphate dihydrate (Ph. Eur.), water for injections.

Indications
For the treatment of first and second degree haemorrhoidal disease.

Contraindications
Sclerotherapy of haemorrhoidal disease is absolutely contraindicated in patients with:

– known allergy to lauracromogol 400 or any of the other ingredients of Anthoxyklon®
– acute severe systemic disease (especially if untreated)
– acute inflammations in the anal region.
Depending on severity, sclerotherapy of haemorrhoidal

disease may be relatively contraindicated in patients with:

– febrile states
– bronchial asthma or known strong predisposition to allergies
– very poor general health
– chronic inflammatory bowel disease (e.g. Crohn's disease)
– known hypercoagulability.

Adverse drug reactions
Sclerotherapy of haemorrhoidal disease, local adverse reactions such as burning, pain, discomfort, and pressure sensation were observed during and after injection, especially in the 11 o'clock position in men (prostate region). These reactions are of a temporary

nature and may last 2-3 days in rare cases. Sclerotherapy of haemorrhoids is painless if the proper technique is used since there are no sensitive nerve fibres in the region of injection. In addition, the following adverse reactions were observed with the frequency seen below (information given according to MedDRA (Medical Dictionary for Regulatory Activities):
Very common (≥ 10%); common (≥ 1% – < 10%); uncommon (≥ 0.1% – < 1%); rare (≥ 0.01% – < 0.1%); very rare, including isolated cases (< 0.01%):
Uncommon: dermatitis allergic, urticaria, contact, skin reaction
Very rare: anaphylactic shock, angioedema, urticaria (generalized), asthma (asthmatic attacks)
Nervous system disorders
Very rare: loss of consciousness, confusional state, dizziness

Cardiac disorders
Very rare: palpitations
Vascular disorders
Very rare: syncope vasovagal, circulatory collapse
Gastrointestinal disorders
Uncommon: proctitis, anal pruritus
Very rare: nausea
Skin and subcutaneous tissue disorders
Uncommon: dematitis allergic, urticaria, contact, skin reaction
Reproductive system and breast disorders
Very rare: erectile dysfunction
General disorders and administration site conditions
Common: burning sensation mucosal, injection site pain, discomfort, sensation of pressure
Uncommon: induration

Special warnings and precautions for use
All Anthoxyklon products contain 5% (w/v) alcohol. This must be taken into account in patients with previous alcoholism.
Anthoxyklon products contain potassium, but less than 1 mmol (39 mg potassium) per ampoule.
Anthoxyklon products contain sodium, but less than 1 mmol (23 mg sodium) per ampoule.
Sclerotherapy of haemorrhoidal disease
When treating haemorrhoidal disease, care must be

taken not to damage the internal anal sphincter muscle in order to avoid incontinence problems. When treating an 11 o'clock haemorrhoid in men, the quantity injected must not exceed 0.5 ml.
Anthoxyklon 3% because of the proximity to other structures (urethra and prostate).

Pregnancy and breast-feeding
Pregnancy
There are no adequate data from the use of Anthoxyklon in pregnant women. Studies in animals showed reproductive toxicity, but no teratogenic potential. Therefore, Anthoxyklon must not be used during pregnancy unless clearly necessary.
Breast-feeding
Investigations on the possible excretion of lauracromogol 400 in the breast milk have not been per-

formed in humans. If sclerotherapy is necessary during breast-feeding, it is advisable to suspend breast-feeding for 2-3 days.

Classification for supply
Medicinal product subject to medical prescription.

Date of revision of the text
July 2009

Dosage and method of administration
The injection must be strictly subcutaneous and given directly into the haemorrhoid or above it into the surrounding tissue of the feeding vessels. During one treatment session, a total of 3 ml Anthoxyklon 3% should not be exceeded. Depending on the findings, a maximum of 1.0 ml per haemorrhoid is administered as a strictly subcutaneous injection. When treating an 11 o'clock haemorrhoid in men, the quantity injected must not exceed 0.5 ml. Depending on the degree of haemorrhoidal disease, several repeat treatments may be required.

Anthoxyklon 3% is available as solution for injection in packs of 5 ampoules of 2 ml each.



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