VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Itching and pain of the anus or perianal skin is a common disorder usually arising from benign conditions. Approximately 75% of cases of anal pruritus are secondary to inflammatory, infectious, neoplastic, and anorectal disorders that contribute to the development of pruritus, including haemorrhoids, fissures, abscesses, fistulas. However, their prevalence is difficult to estimate since almost any anorectal discomfort is often attributed to symptomatic haemorrhoids.

The worldwide prevalence of symptomatic haemorrhoids is estimated at 4.4%. Other studies indicate prevalence up to up to a 30%–40% in the United States. Overall it is estimated that 50% of the population will experience symptomatic haemorrhoid at some point in their lives.

Risk factors associated with certain perianal diseases such as haemorrhoids, anal fissures and fistulas are: age, associated co-morbidities (e.g. colon malignancy, hepatic disease, loss of rectal muscle tone, inflammatory bowel disease), obesity, pregnancy, rectal surgery, episiotomy, chronic constipation and sedentary lifestyle.

VI.2.2 Summary of treatment benefits

Lidocaine KGV 50 mg/g rektalsalva is indicated for the symptomatic treatment of itching and pain in the anal region, e. g. due to haemorrhoidal disorders. Lidocaine is a local anaesthetic of the amide-type family which limits the pain, cold, heat, touch and pressure sensitivity locally and decreases it reversibly, being effective against wound pain and pruritus.

Lidocaine KGV 50 mg/g rektalsalva has been in use worldwide for decades in a variety of clinical situations, meeting the requirements of a well-established use medicinal product in terms of safety and efficacy. Clinical trials have been conducted with lidocaine 50 mg/g ointment in the relief of symptoms of haemorrhoids showing the efficacy and tolerability for the treatment of anorectal itching after administering 125 mg/dose, 2-3 times daily. Lidocaine has also proved to be efficacious for the management of pain in different anorectal conditions such as fissures and proctitis and before anorectal examinations like transrectal ultrasound prostate biopsies or after haemorrhoidectomy.

VI.2.3 Unknowns relating to treatment benefits

In the main and supporting studies nearly all patients were Caucasians. There is no evidence to suggest that results would be any different in younger or elderly patients. In fact, the systemic availability of topical lidocaine did not differ between young and elderly adults in some study.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Local hypersensitivity reactions (e. g. contact dermatitis)	Local allergic reactions at the site of administration, such as allergic contact dermatitis are very common side effects. Allergic contact dermatitis usually appears within 24 to 72 hours. The area affected is limited to tissue that was in direct contact with lidocaine.	No. However, although the severity and frequency of these events is unpredictable and variable between patients, these conditions are generally reversible and patients who develop these symptoms are instructed to reduce and/or cease use of the product and to seek further medical advice.

Missing information

Risk	What is known
Use during pregnancy or lactation	No data exist on penetration of Lidocaine KGV 50 mg/g rektalsalva into the placenta or the breast milk. To date no harmful effects on the fetus have been reported. However, Lidocaine KGV 50 mg/g rektalsalva should not be applied during pregnancy or lactation unless clearly indicated.

VI.2.5 Summary of risk minimisation measures by safety concern

Currently, it is considered that the safety profile of Lidocaine KGV 50 mg/g rektalsalva in its proposed indication is well characterised and there are no gaps in knowledge about its safety in the target population; hence, routine pharmacovigilance activities are deemed adequate to ensure the minimisation of potential risks of the product. No additional risks minimisation measures are considered necessary for Lidocaine KGV 50 mg/g rektalsalva use at this stage.

VI.2.6 Planned post authorisation development plan

Neither planned studies, nor studies imposed by the Committee for Medicinal Products for Human Use (CHMP)/National Competent Authorities (NCA) are foreseen for this product.

List of studies in post authorisation development plan

Not applicable.

Studies which are a condition of the marketing authorisation

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.