

COMPOUNDING IMIQUIMOD SUPPOSITORIES FOR CONDILOMA ACUMINATA

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Background and importance

Condylomata acuminata (CA), or anogenital warts, are typically found on the penis, vulva, perianal skin and rectal mucosa. Topical imiquimod 5% cream containing 12.5 mg per sachet is a first-line treatment option for external CA. However, its efficacy and safety can be compromised by the difficulty of administration in the anal canal.

Aim and objectives

To review the scientific literature of imiquimod suppository compounding formulations and to compound suppositories of imiquimod 12.5 mg

Materials and methods



A literature review was carried out in PubMed and Embase using "Imiquimod," "suppository," and "anal" as keywords. Only clinical studies were analyzed.

Ingredients, equipment, method of preparation, quality control, packaging, and labeling were described.

Results



Imiquimod suppositories were used in four of the seven identified clinical studies. Three of them were observational studies, and one was a clinical trial. However, none explained how to compound imiquimod suppositories.



Ingredients for 240 imiquimod 12.5 mg suppositories included: imiquimod 3 g, massa esteranium 637 g as suppository base (no calculations for dose replacement were needed)



Equipment: analytical balance, beaker, porcelain mortar and pestle, suppository mold. Personal protective equipment: gloves, gown, eye protection, FFP2 mask. Environment: cleanroom, class one laminar flow hood.



Method: 1) bring mold to room temperature. 2) Weigh imiquimod powder. 3) Melt suppository base using microwaves. 4) Disperse imiquimod in melted base using mortar and pestle. 5) Pour mixture into mold cavities (no lubricant needed). 6) Cool mold in refrigerator for one hour. 7) Remove excess material from mold top using a spatula.



Quality control: weight variation +/- 5% and visual observation. Package in a tight, light-resistant container and label. Beyond-use date: six months.

Conclusion and relevance

Variability in imiquimod formulations likely caused contradictory results in the efficacy and tolerability of imiquimod suppositories for CA.

Administering imiquimod suppositories following this preparation method may improve efficacy and safety in patients with CA who have difficulties or aversion to administering imiquimod cream in the anal canal.



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