SpecializedRx
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SUGGESTED PROCEDURE

Item	Methimazole 5mg/0.1ml Transdermal Gel	Formula Date	11 Mar 2024
API(s)	Methimazole, USP	Procedure No.	P2646
Base	VersaPenn™ AG Gel	Revision	R1
Volume/Quantity	100g	Compound Type	Anhydrous Topical

Rx	Weight (g)	Percent	Comment
Methimazole, USP	5g	5%	
Propylene Glycol, NF	1ml	1%	
VersaPenn™ AG	94g	94%	qs
Total	100g	100%	

To account for processing error considerations during preparation, it is suggested to measure an additional **10%** of the required quantities of ingredients.

Suggested Method of Preparation

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient. Consider batch size and density conversions if required.
3. Triturate Methimazole to a fine powder.
4. Levigate the Methimazole powder with Propylene Glycol to form a homogeneous paste dispersion.
5. Geometrically incorporate the VersaPenn™ AG base and mix well to form a homogeneous gel-like dispersion.
6. Final product should be a uniform translucent gel.
7. Transfer the final preparation into an appropriate dispensing container.
8. Suggested Quality assessments
    a. Appearance and feel
    b. Quantity
    c. Label: auxiliary labels, storage, BUD, compounded medication, for external use only

Packaging: Tight, light-resistant container, syringe, UnoDose™ container.
Estimated Beyond Use Date: 180 days per USP 795*
Labeling: Keep out of reach of children. Use only as directed. Protect from moisture and light.
Stability: Anhydrous formulation.
Note: Potency Range Recommendation: ≥90% and ≤110% of the theoretically calculated active(s).
Note: All products, except for API(s) are sourced from SpecializedRx only. Any deviation from ingredients used will invalidate the formula.

***Beyond-Use Date should be based on the current USP General Chapter <795>.** Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist. Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, and intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date. It is recommended that you follow USP <795> recommendations for potency testing.

WARNING! Precautions should be taken when handling APIs as they can be absorbed through the skin, mucus membranes and lungs if inhaled. Always wear protective lab apparel, gloves, eye protection, respirator / work under a safety cabinet.