ARTWORK

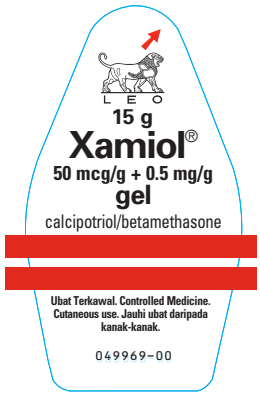
Please return to:
LEO Pharma A/S
Internal Market Access
Industriparken 55 – DK-2750 – Ballerup

Scale	Get-up	Item No.	Rev. No.	Sent by e-mail	
100%	MY	049969	00	▼	
Subject			Date	Date	Date
LBL 50,8 x 28,6 mm			22/03/16		
Colour			Sign.	Sign.	Sign.
PMS 485 + black			DVR		

Preparation Strength	Supplier / Place of production
Xamiol® gel - 15 g - 3 pages	Ireland

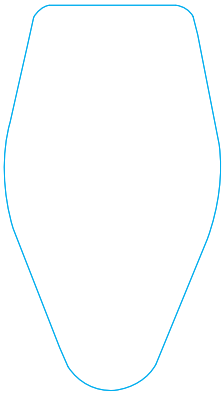
Comments:

1



3





2

2. PROOF FROM RBE	Artwork Approval Stamp (AAS)		
Date 01/04/16	**Graphic Design**	**Second Approver**	**Market Regulatory Approval**
New proof requested ☐	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Product name ☐	National Legislation ☐
		Dosage form ☐	Marketing Authorisation ☐
Sign.:	Sign.: Date:	Strength/Stripes ☐	Relevant languages ☐
		Pack size ☐	Sign.: Date:
		Prompts ☐	
	Editorial Proof	Material No./Reg. No. ☐	
Date:	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Barcode ☐	Printed name *(in CAPITAL letters or LEO ID)*:
	Sign.: Date:	Sign.: Date:	

ARTWORK

Please return to:
LEO Pharma A/S
Internal Market Access
Industriparken 55 – DK-2750 – Ballerup

Scale	Get-up	Item No.	Rev. No.	Sent by e-mail	
100%	MY	031093	XX	▼	
Subject			Date	Date	Date
LBL 50,8 x 28,6 mm			18/05/16		
Colour			Sign.	Sign.	Sign.
PMS 485 + black			RBE		

Preparation Strength	Supplier / Place of production
Xamiol® Gel - 15 g - back - 3 pages	Ireland

Comments:
Mock-up for registration purpose.

1

Shake the bottle before use.

Keep out of the reach and sight of children.

Do not refrigerate.

Do not store above 30°C.

Keep the bottle in the outer carton in order to protect from light.

LOT/MAN/EXP
- see the bottom of the bottle.

Discard 3 months after first opening.

031093-XX

3

Active substances:
One gram of gel contains 50 microgram of calcipotriol (as hydrate) and 0.5 mg of betamethasone (as dipropionate).
Other ingredients:
Paraffin liquid, polyoxypropylene stearyl ether, hydrogenated castor oil.

See leaflet for further information.

031093-XX

2

Do not apply directly to the face or eyes.

Wash hands after use.

Read the package leaflet before use.

Cutaneous use.

For external use only.

Mock-up Approval Stamp (MAS)

1. PROOF FROM RBE	Graphic Design	Editorial Proof	Second Approver
Date 18/05/16	**According to:** Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 ☐	**According to:** Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 ☐	Product name ☐
New proof requested ☐			Dosage form ☐
Sign.:			Strength/Stripes ☐
			Pack size ☐
Date:	Sign.: Date:	Sign.: Date:	Prompts ☐
			Material No./Reg. No. ☐
			Barcode ☐
			Sign.: Date:

ARTWORK

Please return to:
LEO Pharma A/S
Internal Market Access
Industriparken 55 – DK-2750 – Ballerup

Scale	Get-up	Item No.	Rev. No.	Sent by e-mail	
100%	MY	049971	00	▼	
Subject			Date	Date	Date
LBL 65,1 x 34,9 mm			22/03/16		
Colour			Sign.	Sign.	Sign.
PMS 485 + black			DVR		

Preparation Strength	Supplier / Place of production
Xamiol® gel - 30 g - 3 pages	Ireland

Comments:
3 pages

1

30 g

Xamiol®
50 mcg/g + 0.5 mg/g
gel
calcipotriol/betamethasone

Ubat Terkawal
Controlled Medicine
Cutaneous use
Jauhi ubat daripada kanak-kanak

049971-00

3

Product Registration Holder:
DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm No.1,
Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor.

Manufactured by:
LEO Laboratories Ltd
285 Cashel Road
Crumlin, Dublin 12
Ireland

MAL10120015AZ

LEO
049971-00

2

4. PROOF FROM RBE	Artwork Approval Stamp (AAS)		
Date 01/04/16	**Graphic Design**	**Second Approver**	**Market Regulatory Approval**
New proof requested ☐	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Product name ☐	National Legislation ☐
Sign.:	Sign.: Date:	Dosage form ☐	Marketing Authorisation ☐
		Strength/Stripes ☐	Relevant languages ☐
		Pack size ☐	Sign.: Date:
		Prompts ☐	
	Editorial Proof	Material No./Reg. No. ☐	
Date:	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Barcode ☐	Printed name *(in CAPITAL letters or LEO ID)*:
	Sign.: Date:	Sign.: Date:	

ARTWORK

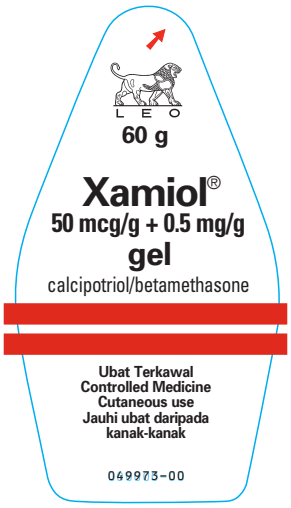
Please return to:
LEO Pharma A/S
Internal Market Access
Industriparken 55 – DK-2750 – Ballerup

Scale	Get-up	Item No.	Rev. No.	Sent by e-mail	
100%	MY	049973	00	▼	
Subject			Date	Date	Date
LBL 65,1 x 34,9 mm			22/03/16		
Colour			Sign.	Sign.	Sign.
PMS 485 + black			DVR		

Preparation Strength	Supplier / Place of production
Xamiol® gel - 60 g - 3 pages	Ireland

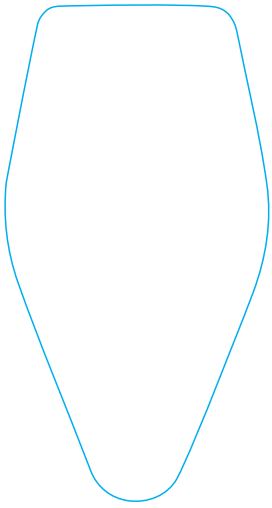
Comments:
3 pages

1



3





2

4. PROOF FROM RBE	Artwork Approval Stamp (AAS)		
Date 01/04/16	**Graphic Design**	**Second Approver**	**Market Regulatory Approval**
New proof requested ☐	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Product name ☐	National Legislation ☐
		Dosage form ☐	Marketing Authorisation ☐
Sign.:	Sign.: Date:	Strength/Stripes ☐	Relevant languages ☐
		Pack size ☐	Sign.: Date:
		Prompts ☐	
	Editorial Proof	Material No./Reg. No. ☐	
Date:	**According to:** Instruction For Use, Artwork Approval Stamp (AAS) SOP_000647 and SOP_000962 ☐	Barcode ☐	Printed name *(in CAPITAL letters or LEO ID):*
	Sign.: Date:	Sign.: Date:	

ARTWORK

Please return to:
LEO Pharma A/S
Internal Market Access
Industriparken 55 – DK-2750 – Ballerup

Scale	Get-up	Item No.	Rev. No.	Sent by e-mail	
100%	MY	031097	XX	▼	
Subject			Date	Date	Date
LBL 65,1 x 34,9 mm			18/05/16		
Colour			Sign.	Sign.	Sign.
PMS 485 + black			RBE		

Preparation Strength	Supplier / Place of production
Xamiol® gel - 30 g + 60 g - back	Ireland

Comments:
3 pages

Mock-up for registration purpose.

1

Shake the bottle before use.

Keep out of the reach and sight of children.

Do not refrigerate.

Do not store above 30°C.

Keep the bottle in the outer carton in order to protect from light.

LOT/MAN/EXP
- see the bottom of the bottle.

Discard 3 months after first opening.

031097-XX

3

Active substances:
One gram of gel contains 50 microgram of calcipotriol (as hydrate) and 0.5 mg of betamethasone (as dipropionate).

Other ingredients:
Paraffin liquid, polyoxypropylene stearyl ether, hydrogenated castor oil.

See leaflet for further information.

031097-XX

Do not apply directly to the face or eyes.

Wash hands after use.

Read the package leaflet before use.

Cutaneous use.

For external use only.

2

1. PROOF FROM RBE	Mock-up Approval Stamp (MAS)		
Date 18/05/16	**Graphic Design**	**Editorial Proof**	**Second Approver**
New proof requested ☐	**According to:** Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 ☐	**According to:** Instruction For Use, Mock-up Approval Stamp (MAS) SOP_000647 and SOP_000962 ☐	Product name ☐
Sign.:	Sign.: Date:	Sign.: Date:	Dosage form ☐
Date:			Strength/Stripes ☐
			Pack size ☐
			Prompts ☐
			Material No./Reg. No. ☐
			Barcode ☐
			Sign.: Date: