



Medicines & Healthcare products  
Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00697**

6 December 2024

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 11 November 2024.  
You wrote:

*I would be grateful if you could advise on the legal basis on which the following Nicotinell licences were registered (initial MAA) and where applicable please can you advise on the product licences that they are referenced from.*

*Nicotinell Icemint 2mg Medicated Chewing Gum Nicotinell Support Icemint 2mg  
medicated Chewing Gum  
Haleon UK Trading Limited  
PL 44673/0120*

*Nicotinell Icemint 4 mg, medicated chewing-gums Nicotinell Support Icemint 4mg  
medicated Chewing Gum  
Haleon UK Trading Limited  
PL 44673/0121*

*Nicotinell fruit 2 mg medicated chewing Gum  
Haleon UK Trading Limited  
PL 44673/0122*

*Nicotinell fruit 4 mg medicated chewing Gum  
Haleon UK Trading Limited  
PL 44673/0123*

*Nicotinell Mint 2mg Medicated Chewing Gum  
Nicotinell Support Mint 2mg Medicated Chewing Gum  
Haleon UK Trading Limited  
PL 44673/0126*

*Nicotinell Mint 4mg Medicated Chewing Gum*  
*Nicotinell Support Mint 4mg Medicated Chewing Gum*  
*Haleon UK Trading Limited*  
*PL 44673/0127*

*Nicotinell Liquorice 2mg medicated chewing gum*  
*Haleon UK Trading Limited*  
*PL 44673/0186*

*Nicotinell Liquorice 4 mg medicated chewing gum*  
*Haleon UK Trading Limited*  
*PL 44673/0187*

*Nicotinell TTS 10 (Transdermal Patch) 7 mg/24 hour*  
*Haleon UK Trading Limited*  
*PL 44673/0128*

*Nicotinell TTS 20 (Transdermal Patch) 14 mg/24 hour*  
*Haleon UK Trading Limited*  
*PL 44673/0129*

*Nicotinell TTS 30 (Transdermal Patch) 21 mg/24 hour*  
*Haleon UK Trading Limited*  
*PL 44673/0130*

*Nicotinell Mint 1 mg compressed Lozenges*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0003*

*Nicotinell Mint 2 mg compressed Lozenges*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0004*

*Nicotinell Fruit 2 mg, medicated chewing-gums*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0005*

*Nicotinell Fruit 4 mg, medicated chewing-gums*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0006*

*Nicotinell Liquorice 2 mg, medicated chewing-gums*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0007*

*Nicotinell Liquorice 4 mg, medicated chewing-gums*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0008*

*Nicotinell Ice Mint 2 mg medicated chewing-gum*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0009*

*Nicotinell Ice Mint 4 mg medicated chewing-gum*  
*GlaxoSmithKline Dungarvan Limited*  
*PL 15545/0010*

## **MHRA Response**

We confirm that we hold the information you have requested. Please see this information overleaf.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

---

## **Your right to complain under the Freedom of Information Act**

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

## **Re-use of our information**

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>

<b>Product Name</b>	<b>Licence Holder</b>	<b>PL Number</b>	<b>Legal Basis of the licence (initial MAA)</b>	<b>Reference licence/product (where applicable)</b>
Nicotinell Icemint 2mg Medicated Chewing Gum Nicotinell Support Icemint 2mg medicated Chewing Gum	Haleon UK Trading Limited	PL 44673/0120	DIR ART 10C	PL 00030/0427 Nicotinell Mint Gum 2mg
Nicotinell Icemint 4 mg, medicated chewing-gums Nicotinell Support Icemint 4mg medicated Chewing Gum	Haleon UK Trading Limited	PL 44673/0121	DIR ART 10C	PL 00030/0428 Nicotinell Mint Gum 4mg
Nicotinell fruit 2 mg medicated chewing Gum	Haleon UK Trading Limited	PL 44673/0122	DIR ART 10.1	PL 00032/0250 Boots NicAssist 2 mg mint gum
Nicotinell fruit 4 mg medicated chewing Gum	Haleon UK Trading Limited	PL 44673/0123	DIR ART 10.1	PL 00032/0251 Boots NicAssist 4 mg mint gum
Nicotinell Mint 2mg Medicated Chewing Gum Nicotinell Support Mint 2mg Medicated Chewing Gum	Haleon UK Trading Limited	PL 44673/0126	DIR ART 10.1	PL 00032/0250 Boots NicAssist 2 mg mint gum
Nicotinell Mint 4mg Medicated Chewing Gum Nicotinell Support Mint 4mg Medicated Chewing Gum	Haleon UK Trading Limited	PL 44673/0127	DIR ART 10.1	PL 00032/0251 Boots NicAssist 4 mg mint gum
Nicotinell Liquorice 2mg medicated chewing gum	Haleon UK Trading Limited	PL 44673/0186	DIR ART 10.1	PL 00032/0250 Boots NicAssist 2 mg mint gum
Nicotinell Liquorice 4 mg medicated chewing gum	Haleon UK Trading Limited	PL 44673/0187	DIR ART 10.1	PL 00032/0251 Boots NicAssist 4 mg mint gum
Nicotinell TTS 10 (Transdermal Patch) 7 mg/24 hour	Haleon UK Trading Limited	PL 44673/0128	Dir Art 4.8a(i)	PL 00001/0161 NICOTINELL TTS 10 TRANSDERMAL PATCH
Nicotinell TTS 20 (Transdermal Patch) 14 mg/24 hour	Haleon UK Trading Limited	PL 44673/0129	Dir Art 4.8a(i)	PL 00001/0162 NICOTINELL TTS 20 TRANSDERMAL PATCH
Nicotinell TTS 30 (Transdermal Patch) 21 mg/24 hour	Haleon UK Trading Limited	PL 44673/0130	Dir Art 4.8a(i)	PL 00001/0163 NICOTINELL TTS 30 TRANSDERMAL PATCH
Nicotinell Mint 1 mg compressed Lozenges	GlaxoSmithKline Dungarvan Limited	PL 15545/0003	Dir Art 4.8 Hybrid	PL 00022/0101 Nicorette 2mg Chewing Gum

Nicotinell Mint 2 mg compressed Lozenges	GlaxoSmithKline Dungarvan Limited	PL 15545/0004	Dir Art 4.8 Hybrid	PL 00030/0146 NICOTINELL MINT LOZENGES 1MG
Nicotinell Fruit 2 mg, medicated chewing-gums	GlaxoSmithKline Dungarvan Limited	PL 15545/0005	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum
Nicotinell Fruit 4 mg, medicated chewing-gums	GlaxoSmithKline Dungarvan Limited	PL 15545/0006	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum
Nicotinell Liquorice 2 mg, medicated chewing-gums	GlaxoSmithKline Dungarvan Limited	PL 15545/0007	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum
Nicotinell Liquorice 4 mg, medicated chewing-gums	GlaxoSmithKline Dungarvan Limited	PL 15545/0008	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum
Nicotinell Ice Mint 2 mg medicated chewing-gum	GlaxoSmithKline Dungarvan Limited	PL 15545/0009	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum
Nicotinell Ice Mint 4 mg medicated chewing-gum	GlaxoSmithKline Dungarvan Limited	PL 15545/0010	Dir Art 4.8a(iii)	PL 00022/0101 Nicorette 2mg Chewing Gum