



1. Product Summary

1.1 Name of the Medicinal Product

Skin Tattooing Ink, Black, 10 x 0.5ml.

1.2 Qualitative and Quantitative Composition

Contains sterilised undiluted black Indian Kandahar Ink.

1.3 Pharmaceutical Form

Sterile solution for tattooing purposes.

2. Clinical Particulars

2.1 Therapeutic Indications

Disclaimer: There are no licensed indications for the use of this unlicensed product. It is the prescriber's responsibility to ensure that this product meets the specific clinical needs of the patient and that the product specification is appropriate to that use. The following uses of this and similar products have been cited in literature sources and reported by various practitioners. These indications are not inclusive and other uses may be considered where appropriate.

The ink is used to produce permanent tattoos as an aid to curative radiotherapy of localised cancer and the endoscopic marking of colonic or oesophageal lesions.

In radiotherapy, the ink is used to produce coplanar tattoo markers on the skin. These markers are used to customise the radiation dose fields to the three-dimensional shape of the tumour target and to align the radiation beams so that discrete doses of radiation are delivered to the diseased tissue. The tattoo is usually a small cross or a group of dots on the skin. However, it should be noted that during the course of treatment, tumour motion and the body surface profile may change causing the position of the reference skin tattoos to move and affect the precision of the pre-treatment set ups.

Endoscopic tattooing is used to mark colonic lesions to assist in operative localisation and as a long term mucosal marker for accurate re-localisation of mucosal abnormalities such as those seen in ulcerative colitis or after polypectomy.

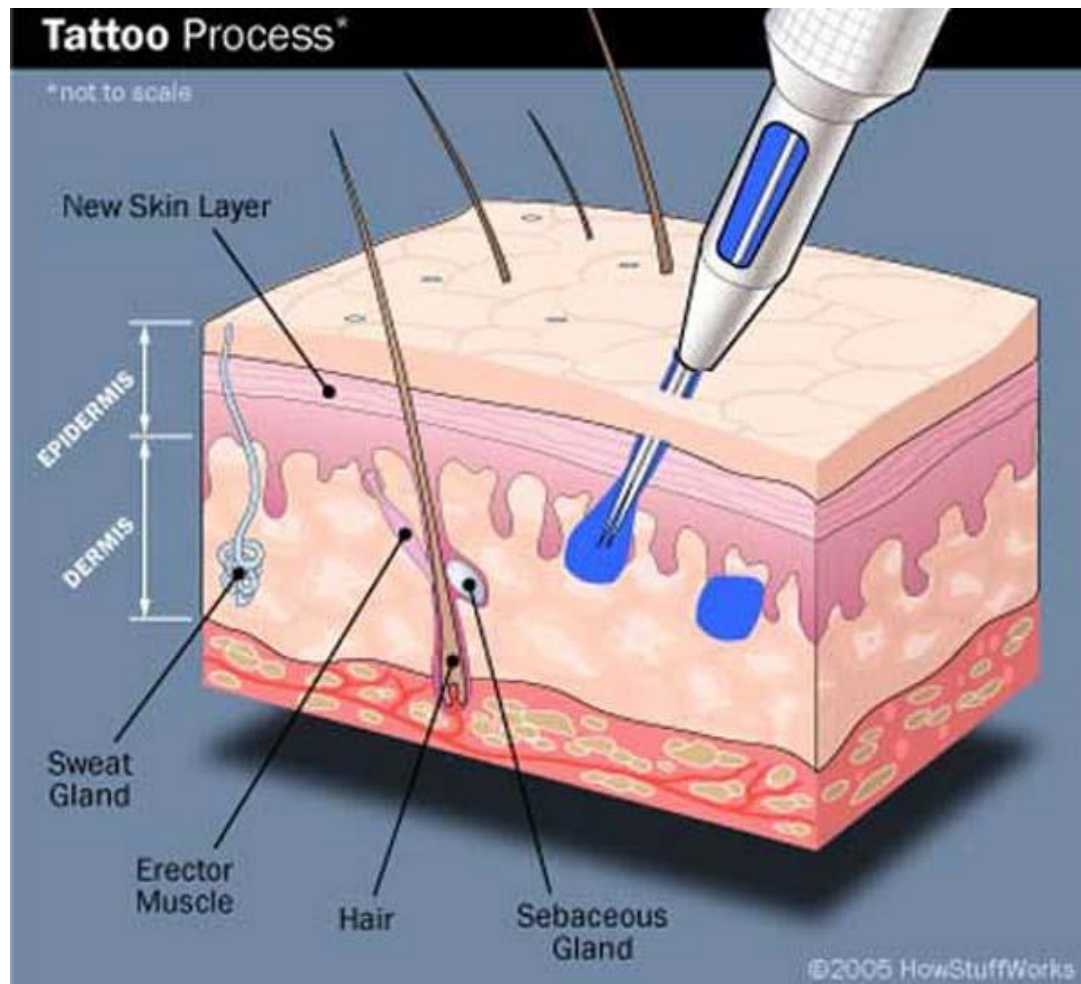
Written by		Date:		Review Date: 3 years from date of QC Authorisation	STAMP AREA
Authorised by (Production)		Date:		T:\CSS_CCRadiotherapy\Quality Management System Documentation\Risk Assessment\COSHH\COSHH Assessments\Safety Data forms\Huddersfield Tattoo Ink.doc 30/06/2021	
Authorised by (Quality Control)		Date:			
Issued for use by		Date		Page 1 of 5	

The ink has also been used for endoscopic marking of oesophageal lesions, in particular Barrett's Oesophagus.


2.2 Method of Administration

The route of administration depends on the part of the body that is to be tattooed. The tattoo process is the same in each case and involves the permanent deposition of pigment into the skin by the use of a tattooing needle or tattooing device.

For skin tattoos, the ink solution (pigment) is permanently deposited to a depth of approximately one to two millimetres into the dermis by **intra-dermal injection**. The actual depth varies from person to person. Pigment deposited in the layer of skin over the dermis, the epidermis, will be lost as the epidermis grows and is exfoliated.



<p>CONTINUATION PAGE</p>	<p>Review Date: 3 years from date of QC Authorisation</p>	<p>STAMP AREA</p>
	<p>T:\CSS_CC\Radiotherapy\Quality Management System Documentation\Risk Assessment\COSHH\COSHH Assessments\Safety Data forms\Huddersfield Tattoo Ink.doc 30/06/2021</p>	
	<p>Page 2 of 5</p>	

	Calderdale & Huddersfield NHS Foundation Trust Pharmacy Manufacturing Unit Acre Mill Site	
	Unlicensed Medicines Information Leaflet	Revision: B

In endoscopic tattooing, the ink solution (pigment) is delivered through an injection needle passed through the working channel of the endoscope and injected by **submucosal injection**. The needle should be inserted at an oblique angle to the colon wall to avoid penetrating the serosa. Once the needle's bevel is within the submucosa an injection is made raising a bleb. Care should be taken to avoid needle puncture through the bowel wall.

The contents of the ampoule should be shaken before use to ensure the colloidal material in the ink is fully suspended.

The ink may be diluted, if necessary, with sterile Sodium chloride 0.9% w/v injection solution. Tattoos created with Indian ink injected at 1:100 concentration and in 0.5ml aliquots have been reported to produce no gross inflammation and to be visible at colonoscopy, laparoscopy and laparotomy for up to 5 months.

Ref: Endoscopic tattooing – Technical Status Evaluation. Gastrointestinal Endoscopy. 2002. Vol. 55 (7), 811 – 814.

3. Pharmaceutical Particulars

3.1 List of Excipients

The ink is prepared by Daler-Rowney, a company specialising in the manufacturing of inks. The ingredients are listed as:

Water, Carbon Black pigment (in aqueous pigment dispersion), Shellac, Borax, Acticide FSN (preservative – less than 0.2%) and Acticide NBF-50 (preservative – less than 0.2%).

The ingredients are not considered by the manufacturer in their Health & Safety Data Sheet to present a hazard to health within the meaning of the Dangerous Substances Directive 67/548/EEC. The final product is certified as free from TSE – Transmission of Spongiform Encephalitis.

3.2 Incompatibilities

None known.

3.3 Shelf Life

2 years

3.4 Special Precautions for Storage

Store below 25°C. Protect from light. Keep out of the reach and sight of children.

CONTINUATION PAGE	Review Date: 3 years from date of QC Authorisation	STAMP AREA
	T:\CSS_CC\Radiotherapy\Quality Management System Documentation\Risk Assessment\COSHH\COSHH Assessments\Safety Data forms\Huddersfield Tattoo Ink.doc 30/06/2021	
	Page 3 of 5	

	Calderdale & Huddersfield NHS Foundation Trust Pharmacy Manufacturing Unit Acre Mill Site	
	Unlicensed Medicines Information Leaflet	Revision: B

3.5 Nature of Container and Closure


2ml clear, type I glass ampoule
Outer: 10 x 0.5ml ampoule box.

3.6 Labels

Primary container label

<p>0.5ml</p> <p>SKIN TATTOOING INK (BLACK)</p> <p>For intradermal or submucosal injection.</p> <p>Shake well before use</p> <p>Batch No:000000 Use Before:00.XXX.0000 Huddersfield Royal Infirmary PMU MS 19055/01 SKI 0 1 S C 0 0 0 1</p>

Secondary container label

<p>10 x 0.5ml</p> <p>SKIN TATTOOING INK BLACK</p> <p>(Sterile Indian Kandahar Ink)</p> <p>FOR INTRADERMAL OR SUBMUCOSAL INJECTION</p> <p><small>Inject intradermally for cutaneous tattoos. For colonic or oesophageal tattooing inject by submucosal injection. The ink may be diluted with sterile sodium chloride 0.9% w/v injection if necessary. Shake well before use.</small></p>	<p>KEEP OUT OF THE REACH AND SIGHT OF CHILDREN</p> <p>Store below 25° C. Protect from light</p> <p>Batch No:000000 Use Before:00.XXX.0000</p> <p>MS 19055/01 Huddersfield Royal Infirmary PMU Tel: 01484 355388</p> <p>SKI01SXC 0 0 0 1</p>	 <p>5 055215 660193</p>
--	--	---

<p>CONTINUATION PAGE</p>	<p>Review Date: 3 years from date of QC Authorisation</p>	<p>STAMP AREA</p>
	<p>T:\CSS_CCRadiotherapy\Quality Management System Documentation\Risk Assessment\COSHH\COSHH Assessments\Safety Data forms\Huddersfield Tattoo Ink.doc 30/06/2021</p>	
	<p>Page 4 of 5</p>	



3.7 Special Precautions for Disposal and Other Handling

Dispose of as pharmaceutical waste.

4. Administrative Data

4.1 Manufacturer

Calderdale & Huddersfield NHS Foundation Trust,
Pharmacy Manufacturing Unit, Gate 2, Acre Mills, School Street, Lindley,
Huddersfield, West Yorkshire, HD3 3ET

4.2 Manufacturing Authorisation

MS 19055/01

4.3 Legal Category

Unlicensed medicine

4.4 Product Code

SKI01S

4.5 Barcode – EAN13

5055215660193

4.6 Date of Specification Authorisation

01.JAN.2012

4.7 Date of Specification Review

01.JAN.2015

Copyright © 2011 The Pharmacy Manufacturing Unit, Calderdale & Huddersfield NHS
Foundation Trust, All rights reserved.

CONTINUATION
PAGE

Review Date: 3 years from date of QC Authorisation

T:\CSS_CCRadiotherapy\Quality Management System Documentation\Risk
Assessment\COSHH\COSHH Assessments\Safety Data forms\Huddersfield
Tattoo Ink.doc 30/06/2021

Page 5 of 5

STAMP AREA