Perfectha®

Summary of Safety and Clinical Performance (SSCP – Switzerland only)

P.MDD.SSCP.01

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HEALTHCARE PROFESSIONAL SECTION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of Perfectha.

The SSCP is not intended to replace the Instructions for Use (IFU) which is considered to be the main document to ensure safe use of Perfectha, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1 IDENTIFICATION DEVICE AND MANUFACTURER

1.1 Trade Name

Perfectha®

1.2 Legal Manufacturer

Sinclair France S.A.S, located at:

8 Chemin du Jubin
69570 Dardilly
France

1.3 Basic UDI-DI

Perfectha Deep: 506003304362718096140 40ND
Perfectha Derm: 506003304453627180961 40PS
Perfectha Finelines: 506003304180961406021 30J9
Perfectha Subskin: 506003304271809614091 91MV

1.4 Medical device nomenclature

GMDN 59131, Dermal tissue reconstructive material, microbe-derived

1.5 Classification

Medical Device Directive (MDD) 93/42/EEC (as amended) Annex IX, Medical Device Class III, Rule 8. Perfectha is therefore a Medical Device Class III.

1.6 CE Marking

Under Annex IX of Medical Device Directive (MDD) 93/42/EEC Perfectha Finelines, Perfectha Derm and Perfectha Deep have been CE marked since 2007, by Obvieline, now known as Sinclair France. Perfectha Subskin was CE marked in 2010. Sinclair France has been a subsidiary of Sinclair Pharma Ltd since January 2014.

1.7 Swiss Authorised Representative

Sinclair Pharma GmbH, Heidelberg (Deutschland) located at:
Zweigniederlassung Gossau SG
Industriestrasse 149, 9200 Gossau SG

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1.8 Notified Body

Szutest Uygunluk Degerlendirme A.S.
Tatlisu Mah.
Akif Inan Sk. No: 1
Ümraniye 34774 -Istanbul, Turkey

Notified Body Number: 2195

2 INTENDED USE OF THE DEVICE

2.1 Intended Purpose

Perfectha is a resorbable hyaluronic acid (HA) gel implants intended for reconstructive purposes in the treatment, for instance, of facial lipoatrophy, or morphological asymmetry associated with the aging process or other underlying conditions. Perfectha is for intradermal and subcutaneous application and is implanted in the areas of the face and hands to fill skin depressions and also for the augmentation of tissue volume.

It is supplied in a sterile, single-use syringe with cross-linked hyaluronic acid gel.

2.2 Indication

As per section 2.1, Intended Purpose.

2.2.1 Target Population

Perfectha is intended to be used in adult patients (over 18) whom are not pregnant or breast-feeding and are deemed appropriate for treatment by the healthcare professional.

2.3 Contraindications

Refer to the IFU (available on request).

3 DEVICE DESCRIPTION

3.1 Device Description

Perfectha is an implantable, resorbable, sterile cross-linked hyaluronic acid (HA) gel of non-animal origin. Each device in the Perfectha family is designed for different application areas and/ or depths, consequently the devices are provided with the needle best suited for use with each device in its intended application area.

The application areas are detailed in Table 1.

Table 1 Product Range Description

Product	Application areas
Perfectha FineLines	For intradermal injection. Filling of superficial lines and depressions, i.e., periorbital and peribuccal fine lines. For use in the tear troughs by injection into the supraperiosteal plane
Perfectha Derm	For superficial subcutaneous injection. Filling of medium lines and depressions, i.e., nasolabial folds and marionette lines, for lip enhancement and scars.
Perfectha Deep	For subcutaneous injection. Filling of deep lines and depressions, i.e., nasolabial folds and marionette lines. For moderate contouring and volumisation in areas of cheekbones, chin, jawline, temples, nose, sub-orbicularis oculi fat (SOOF) and lip augmentation.
Perfectha Subskin	For deep subcutaneous to supraperiosteal injection. For significant loss of volume in areas such as the cheekbones, chin, jawline, temples, forehead, bridge of the nose and hands.

3.2 Product History

Refer to section 1.6.

3.3 Accessories

Perfectha Finelines and Perfectha Derm are supplied with 30G needles, Perfectha Deep is supplied with 27G needles and Perfectha Subskin is supplied with 25G needles, which are purchased as CE marked devices.

3.4 Combinations

Perfectha is not required to be used in combination with any other device to meet its intended purpose. It is considered a stand-alone device.

4 RISKS and WARNINGS

4.1 Residual Risks and Undesirable Effects

The warning instructions have been applied following a comprehensive risk assessment which has been carried out in accordance with the latest and relevant international standard, ISO 14971 and no residual risks remain.

Perfectha devices have been deemed suitable for use in adults based on the safety profile of the products and their equivalents and the small numbers of adverse events (AE) associated with use. Any undesirable side-effect constitutes an acceptable risk when weighed against the performances intended.

4.1.1 Side Effects/ Adverse Events

Refer to the IFU (available on request).

4.2 Warnings and Precautions

4.2.1 Warnings

Refer to the IFU (available on request).

4.2.2 Precautions for Use

Refer to the IFU (available on request).

4.3 Field Safety Corrective Action (FSCA), Field Safety Notice (FSN)

Perfectha has not been the subject of any FSCA’s or FSN’s at this time.

5 SUMMARY OF CLINICAL EVALUATION

5.1 Summary of Clinical Data from Equivalent Devices

The data presented within the Clinical Evaluation Report (CER) is based on an analysis of available clinical literature and post market clinical data relevant to the intended use and the clinical experience of Perfectha and/ or products with equivalent design characteristics.

Equivalent devices are identified from literature and detailed within the report, and are based on their clinical equivalence, critical attributes, technical and biological equivalence. Clinical studies on the identified devices demonstrated clinical efficacy, and safety and performance of the devices are confirmed.

5.2 Summary of Clinical Data of the Device

Studies assessing the safety and performance of Perfectha provide pivotal data supporting the device range. Summary information from all studies on Perfectha is shown in Table 2.

Table 2 Perfectha clinical studies

Study (n)	Products	Duration of Effect
Kalil et al. (2011) (n=20)	Derm	Upper lip margin Nasolabial folds (12 months)
Laboratoire ObvieLine, (2006) (n=40)	Derm and Deep	Sulcus of labial commissure Lips Nasolabial folds (180 days)
Laboratoire ObvieLine, (2006a) (n=204)	Deep	Marked nasolabial folds (6 months)
Laboratoire ObvieLine, 2007 (n=54)	Derm and Deep	Nasolabial folds Sulcus of labial commissure Labial contour (Minimum 3 months)
Resende et al. (2008) (n=1,366)	Derm and Restylane	Nasolabial folds, lips, ear lobes, cheeks, other (8-12 months)
De Arruda et al. (2008) (n=33)	Derm and Deep	Nasolabial folds Lips (Minimum 3 months)
Regazzini and Fares (2008) (n=126)	Subskin	Chin Cheeks (18 months)
Ami (2009) (n=36)	Subskin	Malar Chin correction (18 months)
Pinzon et al. (2010) (n=30)	SubSkin	Moderate, severe, and extreme nasolabial folds (9 months)
Talarico et al. (2010) (n=87)	Derm	Nasolabial folds and lip correction (6 months)

MDD requires an evaluation of safety and efficacy of the devices to be certified. The CER is performed based on MDD Annex X MEDDEV-Guideline 2.7/1. “Evaluation of Clinical Data”.

Studies on the Perfectha and any equivalent devices have demonstrated effectiveness in a variety of facial conditions or hand rejuvenation with reported effectiveness ranging from 6 months to 3 years with (yearly touch-ups) at 3 years follow-up (Skeie et al. 2010).

Perfectha has an acceptable benefit/risk profile according to current knowledge/ state of the art in the medical fields concerned and according to available medical alternatives.

5.3 Post Market Clinical Follow Up (PMCF)

The adverse event rate for Perfectha is considered to be low and acceptable. The safety profile of Perfectha is well established. Further post market studies are planned.

6 THERAPEUTIC ALTERNATIVES

6.1 Age related volume loss

Dermal filler is a minimally invasive technique that offers a non-permanent alternative to more permanent fillers, laser treatments, or more involved surgical procedures. Dermal fillers, and injectable medical devices are commonly used for facial rejuvenation. Most dermal fillers are passive space filling agents and can be used in facial augmentation, whether used solely or combined (Sherman, 2009).

Since the introduction of the first dermal fillers to the USA in 1981, the practice of minimally invasive facial rejuvenation has grown exponentially. In 2010, US physicians performed more than 1 million injectable HA treatments alone (Breithaupt et al. 2012).

A systematic review on the safety and effectiveness of soft tissue fillers was conducted. The evidence indicated that soft-tissue fillers were effective and well tolerated for correcting nasolabial folds, other moderate to severe wrinkles and folds, and volume loss in cheeks (Hanke et al., 2011).

6.2 HIV Facial lipoatrophy

HIV-associated lipoatrophy affects 40-80% of patients treated with first-generation antiretroviral drugs and still affects a considerable number of HIV-infected patients. The most stigmatizing aspects of HIV-associated lipoatrophy are the cosmetically disfiguring changes affecting facial appearance and leading decreased quality of life, diminished self-esteem, and progressive social withdrawal; occasionally, these changes contribute to a reduction in patients' adherence to antiretroviral therapy, therefore seriously endangering their health. Treatment strategies for HIV-associated facial lipoatrophy include soft tissue augmentation procedures performed using autologous fat grafting or injectable dermal fillers (Becker, 2015).

Social isolation and low self-acceptance may cause depression. Decreased quality of life associated with lipodystrophy may lead to rejection of therapy by patients. HIV-associated lipodystrophy constitutes a threat to human health and life. Applying an optimal method of treatment reduces the stigma associated with facial lipodystrophy and significantly improves patients' quality of life (Szczerkowska-Dobosz et al. 2015).

A systematic review assessed the safety and effectiveness of all filler agents for aesthetic treatment of HIV facial lipoatrophy and provided evidence-based recommendations. HA had intermediate elasticity and viscosity and was able to provide high volumisation properties. Both calcium hydroxylapatite and HA only required one treatment and provided immediate visible improvement, which helped minimise health care and patient cost. HA dermal fillers were an effective and safe treatment and had the advantages of achieving immediate results. These results suggest that HA fillers are safe and effective and similar results would be expected for Perfectha (Jagdeo et al., 2015).

6.3 Atrophic Scars

The treatment of atrophic scars is difficult and dermal filler materials provide a simple alternative with immediate results (Hasson, 2010). Scar formation is an inevitable result of surgery and trauma that results in full thickness epidermal loss (Shilpa et al. 2016).

Acne scars are present in 95% of patients with acne and can cause profound psychosocial morbidity. Dermal fillers are commonly used for facial soft tissue augmentation, and there is increasing interest in their use for the treatment of acne scars, particularly for the atrophic subtype. The evidence for the use of temporary, semi-permanent and permanent fillers for acne scars have been investigated following four studies associated with the use of HA fillers in acne scarring. All studies demonstrated improvement in acne scar appearance with minimal or transient side effects (Forbat, 2017).

Kravvas and Al-Niaimi (2017) assessed the efficacy and adverse reactions of commonly used treatments against post-acne scarring, by assessing the effects of dermal fillers in five studies. All studies supported the safety and efficacy of the dermal fillers like Perfectha and indicates they would be a safe and effective option for the treatment of acne scars.

6.4 Conditions resulting in upper eyelid margin asymmetry

HA dermal fillers can be placed centrally in the subconjunctival levator-muller plane. Alternatively, the injection could be given through the skin. However, it may be more difficult to find the levator plane, because the needle cannot be visualised, and the proper plane is very thin. Care should be taken with levator injections because the globe is in close proximity in this region (Mancini et al. 2011).

7 SUGGESTED PROFILE AND TRAINING FOR USERS

Perfectha should only be used by trained healthcare trained professionals.

The IFU states that ‘This product may be administered only by a registered healthcare professional in accordance with local regulations’ and ‘This device is designed to be injected into the dermis by a healthcare professional who has been specifically trained in injection techniques for dermal filler procedures. The healthcare professional's technical competence is crucial to the success of the treatment.’

Additional training materials are available on request from Sinclair Pharmaceuticals Ltd.

8 APPLIED STANDARDS

Table 3 details the applied standards applied to the device.

Table 3 Applied Standards

Directives
MDD 93/42/EEC (as amended)
EU Regulation No 207/2012
Standards
EN ISO 13485
EN ISO 10993-3
EN ISO 10993-5
EN ISO 10993-9
EN ISO 10993-11
EN ISO 10993-12
EN ISO 10993-13
EN ISO 10993-17
EN ISO 11137-1 & 2
EN ISO 17665-1
EN 556-1
ISO 80369-7
ISO 10993-1
EN ISO 10993-6
EN ISO 10993-10
EN ISO 10993-16
EN ISO 10993-18
EN ISO 11135
EN ISO 11138-1, 3, 7
EN ISO 11607-1 & 2
EN ISO 11737-1
EN ISO 14155
EN ISO 14630
EN ISO 14644-1
EN ISO 14971
ISO 15223-1
EN ISO 15378
EN 17141
ISO/TS 17665-2
EN 1041:2008+A1
EN 62366-1
EN ISO 7864
ISO 639-1
Guidelines
MEDDEV 2.1/1
MEDDEV 2.4/1
MEDDEV 2.7/1
MEDDEV 2.12/2
MEDDEV 2.12/1
ICH guidelines Q1A
GHTF SG5/N2R8

European Pharmacopoeia
Ph.Eur. 2.9.20
Ph.Eur. 2.2.3
Ph.Eur. 2.2.10
Ph.Eur. 2.6.14
Ph.Eur. 2.6.1
Ph.Eur 0002
Ph.Eur. 1472
Ph.Eur. 0227
Ph.Eur. 0193
Ph.Eur. 0194
Ph.Eur. 0602
Ph.Eur. 0169
Ph.Eur. 0008
Ph.Eur. 0677
Ph.Eur. 3.1.8
Ph.Eur. 3.2.1
Ph.Eur. 3.2.2
Ph.Eur. 3.2.9
Ph.Eur 5.1.10

9 CONCLUSION

Perfectha has an acceptable benefit/risk profile according to current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives. Studies on the predecessor product range Perfectha and equivalent devices have demonstrated safety and effectiveness.

The information supplied with the device is reflective of the safe and effective use in its intended applications, the intended purpose and risk reduction measures are acceptable.

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