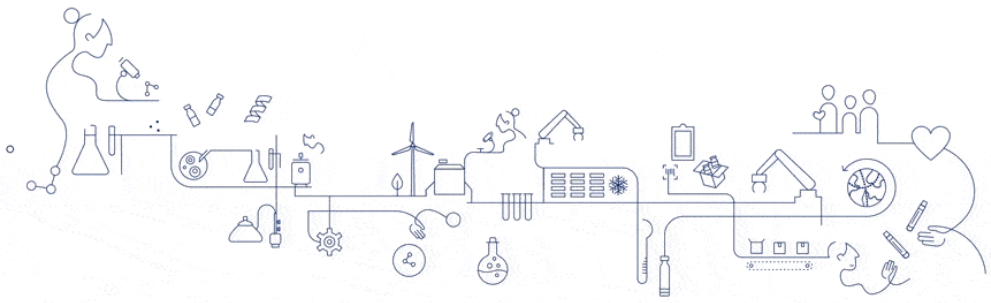
# Icodec in FlexTouch® (incl. API, device and needle)

Product carbon footprint

version 1.0



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Corporate Environmental Strategy

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# 1. Background

Novo Nordisk analyses and understands carbon emissions at the product level. This document presents the Product Carbon Footprint of a one-year treatment of FlexTouch® in combination with icodec, including the use of NovoFine® needle.

Full carbon footprint reports for the API, device and needle are available.

The data presented in this document support marketing claims and Q&As about the product's carbon footprint. The data should not be used for comparison with competitor products or for claims related to 'green' or 'environmentally friendly' products.

# 2. Product carbon footprint methodology

The carbon footprint of a product is calculated by adding the greenhouse gas emissions (in kg $CO_2$ equivalents) from different stages of the product lifecycle as shown in the figure below. The product carbon footprint of one-year treatment is calculated by adding the contributions from the active pharmaceutical ingredient (API), the device and the needle[1].


The Novo Nordisk carbon footprint calculations follow the Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices[2], which is built on international life cycle assessment standards. The reports are third-party reviewed by PricewaterhouseCoopers Advisory.

The carbon footprint calculations are based on production data from 2021 for icodec. Icodec is the active pharmaceutical ingredient (API) in the product Awiqli®, and it is marketed in combination with the existing device FlexTouch® and NovoFine® needles, which third-party verified carbon footprint reports are based on 2019 data, and cover use at three major markets, namely Europe, the US and Japan.

The calculations are made using Excel and the life cycle assessment tool GaBi.

As mentioned before, the icodec FlexTouch® carbon footprint for an average yearly treatment consists of three elements: API, device, and needle. The key assumptions for each of these elements are given below.

[1] Including the packaging for devices and needles.

[2] Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices, GHG Protocol Product Life Cycle Accounting and Reporting Standard, November 2012. At: http://ghgprotocol.org/sites/default/files/ghgp/Summary-Document_Pharmaceutical-Product-and-Medical-Device-GHG-Accounting_November-2012_0.pdf. Accessed May 2021

- **API:** The daily dose is 40 units of insulin, which corresponds to the WHO guidelines[3] for defined daily dose (DDD). The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. As a once-weekly treatment, this would result in an average weekly dose of insulin icodec of 280 units.

- **Device:** FlexTouch® with insulin icodec is provided in different doses with 1.5- or 3.0-ml cartridge, with a 700 U/mL formulation. The cartridges contain thus between 0.4-3.0 ml, corresponding to a unit content of 300-2100 units per cartridge (see Table 1 below). The global average icodec FlexTouch® is estimated to contain 982 insulin units. This average corresponds to the DDD of 40 units of insulin per day (see above) and is therefore the basis of this carbon footprint calculation.

- **Needle:** Novo Nordisk recommends discarding the needle after use. However, market research shows that many patients use the needle several times[4]. To reflect an average patient, the calculations are based on the use of one needle per week (weekly treatment).

Table 1. Description of different variants of icodec in FlexTouch®. The global average variant is calculated based on a weighted average of the different variants with respect to the forecasted sales of each variant. The global average corresponds to the DDD of 40 units of insulin per day as defined by the WHO.

| Variant | Cartridge size | mL content | Formulation | Unit content |
|---|---|---|---|---|
| 1 | 3.0 mL | 3.0 mL | 700 u/mL | 2100 u |
| 2 | 1.5 mL | 1.5 mL | 700 u/mL | 1050 u |
| 3 | 1.5 mL | 1.0 mL | 700 u/mL | 700 u |
| 4 | 1.5 mL | 0.43 mL | 700 u/mL | 300 u |
| Global average | | | | 982 u |

# 3. Product carbon footprint of one-year treatment

The icodec FlexTouch® carbon footprint is 4-7 kg of $CO_2$ equivalents per year, corresponding to 12-19 g $CO_2$ equivalents per day. The main differences are caused by differences in the packaging and distribution scenarios. The results for each of the country scenarios are included in Appendix A.

To put this into perspective for a non-LCA expert, it is possible to compare the carbon footprint to other consumables.

One year of insulin treatment with icodec FlexTouch® corresponds to driving 43-65 km in an average new car in Europe. The $CO_2$ emissions per km data is based on an EU-28 average published by Eurostat[5].

[3] WHO Collaborating Centre for Drug Statistics Methodology (WHOCC): DDD Definition and general considerations. http://www.whocc.no/ddd/definition_and_general_considera/. Accessed Sep 2021.

[4] Roper U.S. Diabetes 2014 Patient Study. Insulin devices market. GFK, November 2014

[5] Eurostat (2022). Average carbon dioxide emissions per km from new passenger cars, https://www.eea.europa.eu/data-and-maps/daviz/average-emissions-for-new-cars-8#tab-chart_1. Accessed July 2023.

It is estimated that the daily environmental impact (using carbon footprint as proxy) of diabetes treatment using icodec FlexTouch®, is lower than a cup of tea. According to Karwacka et al. (2020), a 40-cl cup of tea will result in the emission of 55-102 g $CO_2$ when assessed from cradle to grave[6]. The results are highly sensitive to the tea variety and consumer habits. It must be acknowledged that "a cup of tea" is an ambiguous measure and there are many different types of tea and brewing methods, but the calculation gives a good indication of the size of the impacts related to the treatment of diabetes.

A comparison with air travel shows that the carbon footprint of 45-69 years of treatment with icodec FlexTouch® corresponds to a flight from London to New York. This is calculated based on data from the ICAO Carbon Emissions Calculator[7].

The carbon footprint has inherent uncertainties and should be regarded as an indicative level and not as a precise measure. The uncertainties are related to the data collected from Novo Nordisk production, the data on the carbon footprint for each of the processes (e.g., plastic granulate production), carbon footprint impact factors and the key assumptions (e.g., distribution patterns). Moreover, the calculations consider that Novo Nordisk sources renewable energy through certificates, which results in a lower carbon footprint than if average energy was used.

The plastic footprint of a one-year treatment with icodec FlexTouch® including needles and packaging is 0.33 kg plastic per patient per year[8]. Excluding packaging the plastic footprint of the treatment is 0.28 kg plastic per patient per year.

# 4. Reducing the product carbon footprint

Novo Nordisk strives to reduce its carbon footprint throughout the product lifecycle, and icodec FlexTouch® is produced with the environment in mind.

Our environmental strategy, Circular for Zero, and the certified ISO14001 Environmental Management System drive continuous improvements in our environmental performance by setting high ambitions and integrating environmental considerations into daily business activities. Moreover, life cycle assessment is an integrated part of our device product development process.

Novo Nordisk is using 100% renewable electricity at all production sites[9].

[6] M. Karwackka, A. Ciurzynska, A. Lenart, M. Janowicz (2020). Sustainable Development in the Agri-Food Sector in Terms of the Carbon Footprint: A Review, https://doi.org/10.3390/su12166463

[7] ICAO (International Civil Aviation Organization) (July 2023). Carbon Emissions Calculator. http://www.icao.int/environmental-protection/CarbonOffset/Pages/default.aspx. Accessed July 2023.

[8] Calculated as the plastic contained in the pens and the needles used in the yearly treatment, including primary and secondary packaging.

[9] Novo Nordisk Annual Report 2020, p.12 - https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/ annual_report/2021/Novo-Nordisk-Annual-Report-2020.pdf

# 5. Appendix A: Product carbon footprint results and comparisons

Table 2. Carbon footprint of icodec FlexTouch® for the main markets.

| Market | Carbon footprint of API [kg $CO_2$-eq] | Carbon footprint of device incl. cartridge[10] [kg $CO_2$-eq] | Carbon footprint of needle [kg $CO_2$-eq] | Carbon footprint of one year treatment [kg $CO_2$-eq/yr] | Carbon footprint of daily treatment [g $CO_2$-eq/day] |
|---|---|---|---|---|---|
| **icodec, Europe** | 2.0 | 2.2 | 0.4 | 4.6 | 12.5 |
| **icodec, United States** | 2.0 | 2.4 | 0.4 | 4.8 | 13.2 |
| **icodec, Japan** | 2.0 | 4.5 | 0.5 | 7.0 | 19.0 |

Table 3. Comparison with driving a car. Number of km travelled in an average new car.

| Product Name | EU | US | JP |
|---|---|---|---|
| **icodec U982[11]** | 42.5 | 44.8 | 64.7 |

Table 4. . Comparison with air travel. Years of use correspond to a flight from London to New York.

| Product Name | EU | US | JP |
|---|---|---|---|
| **icodec U982[11]** | 69.1 | 65.6 | 45.4 |

## References

Icodec carbon footprint, Novo Nordisk, July 2023
FlexTouch® carbon footprint, Novo Nordisk, Sep 2021
NovoFine® carbon footprint, Novo Nordisk, Sep 2021

[10] Differences in carbon footprint from the device arise from market and distribution factors. For more details, please see FlexTouch® carbon footprint report, Sep 2021.
[11] Global average. See Section 2, regarding the device.

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# Third party verification of Novo Nordisk Carbon Footprint report for insulin icodec

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**Third party verification of Novo Nordisk Carbon Footprint report for insulin icodec**

**July 28th, 2023**

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Novo Nordisk has commissioned PricewaterhouseCoopers Advisory (PwC) to review several carbon footprint reports for insulin icodec, as well as claims (listed in Appendix) resulting from the reports prepared by Novo Nordisk. The critical review (CR) was done according to the ISO/TS 14 071[1], ISO 14 040[2], ISO 14 044[3] recommendations and also according to the "Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices" recommendations. The CR expert is independent from Novo Nordisk and was not involved in the making of the study. To ensure consistency with the principles and requirements of the standards and guidance (ISO/TS 14 071, ISO 14 040, ISO 14 044, and Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices) on life cycle assessment, the CR was performed by the following LCA experts of PwC: Olivier Muller and Anna Lamy. The conclusions have been provided to Novo Nordisk.

## Nature of the CR work, CR process and limitations

The CR has worked according to the requirements of ISO 14 040:2006, ISO 14 044:2006 and of Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices. The work was conducted throughout July 2023.

The CR of the study appraises the following:

[1] ISO/TS 14071 (2014): Environmental management – Life cycle assessment – Critical review processes and reviewer competencies: Additional requirements and guidelines to ISO 14044 (2006)
[2] ISO 14040 (2006): Environmental management – Life cycle assessment – Principles and framework
[3] ISO 14044 (2006): Environmental management – Life cycle assessment – Requirements and guidelines

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- the methods used are consistent with the standards ISO 14040 and 14044 and Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices;
- the methods used are scientifically and technically valid;
- the data used are appropriate and reasonable in relation to the goal and scope of the study;
- the interpretation reflects the limitations identified and the goal of the study;
- the report is transparent and consistent.

During this period, different oral and written exchanges have been held between PwC and Novo Nordisk, including clarification exchanges regarding the CR comments, and the production of new versions of the carbon footprint reports by Novo Nordisk. Novo Nordisk has taken into account all the comments and has modified and improved its report.

The CR included an assessment of the LCA model, as well as the analysis of a few key individual datasets (relevance, consistency, completeness). It concerns the CR of the following reports:

- "Product Carbon Footprint of an API for diabetes (icodec)", June 2023
- "Product Carbon Footprint of one year treatment of FlexTouch in combination with icodec, including the use of NovoFine needle", July 2023
- Claims related to the new icodec treatment.

The present CR report is the synthesis of the final comments.

The present CR report was prepared by PricewaterhouseCoopers Advisory SA (PwC) for Novo Nordisk. We do not accept or assume any liability or duty of care for any other purpose or to any other person to whom the CR report are shown or into whose hands they may come. The use of their report is the sole responsibility of Novo Nordisk.

We remind you that this CR is only based on facts, circumstances and assumptions which have been submitted to us and which are specified in the CR report. Should these facts, circumstances or assumptions be different, our conclusions might be different.

Moreover, the results of the CR should be considered in the aggregate with regard to the assumptions made and not taken individually.

For all matters of interpretation, the original paper copy of the report takes precedence over any other version.

**Conclusions of the critical review**

**The 2023 icodec study is in conformity with the standards ISO 14040 and 14044 and Greenhouse Gas Accounting Sector Guidance for Pharmaceutical Products and Medical Devices.**

The models of the production systems are understandable, and an important work of updates was done by Novo Nordisk. Cut-off is in line with general cut-off criteria. The allocation principles and allocation procedures are sufficiently described and are justified.

A specific report, which contains all assumptions and choices, helps to reference and to document understandably.

The collected primary data (measurements) is comprehensive. The used data is suitable and in accordance with the goal of the study.

The interpretation of results is neutral and detailed; the gained insights are understandably presented and are in accordance with the goal of the study. The evaluation, interpretation and taken conclusions are valid in the context of the study.

We observe that the report "Product Carbon Footprint of one year treatment of FlexTouch in combination with icodec, including the use of NovoFine needle" relies on the results of underlying reports – including the "FlexTouch", "NovoFine" reports and the "Assumption report" – that will be updated by the end of 2023 to take into account:

- Editorial updates for better clarity of the reports;
- Integration of the most up-to-date lifecycle databases.

Neuilly-sur-Seine (France), July 28th, 2023

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