CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214962Orig2s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	September 29, 2021
Application Type and Number:	NDA 214962
Product Name and Strength:	Tascenso ODT (fingolimod) orally disintegrating tablet, 0.25 mg (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Handa Neuroscience, LLC (Handa)
PNR ID #:	2021-1044724125
DMEPA 2 Safety Evaluator:	Justine Kalonia, PharmD
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Acting Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Tascenso ODT, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Handa did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Handa previously submitted the proposed proprietary name, (b) (4) *** on December 21, 2020. However, we found the name, (b) (4) *** unacceptable due to orthographic and/or phonetic similarities and shared product characteristics with the proprietary names (b) (4), under NDA 214962 on March 19, 2021.[a]

Thus, Handa submitted the name, Tascenso ODT, for review on August 13, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 13, 2021.

- Intended Pronunciation: tuh-SEN-soh ODT
- Active Ingredient: fingolimod
- Indication of Use: treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, (b) (4)
- Route of Administration: oral
- Dosage Form: orally disintegrating tablet
- Strength: 0.25 mg (b) (4)
- Dose and Frequency:
    - (b) (4)
    - pediatric patients (10 years of age and older) weighing less than or equal to 40 kg: 0.25 mg once daily
- How Supplied: carton of 30 orally disintegrating tablets containing 3 blister cards of 10 orally disintegrating tablets per blister card
- Storage: store in the blister pack in a dry place at room temperature between 68°F to 77°F (20°C to 25°C).

[a] Kalonia, J. Proprietary Name Review for (b) (4) *** (NDA 214962). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 19. PNR ID No. 2020-1044427074.

Reference ID: 4866089

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Tascenso ODT.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tascenso ODT would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Tascenso ODT.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Tascenso ODT.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[b].

2.2.2 Components of the Proposed Proprietary Name

Handa did not provide a derivation or intended meaning for the proposed proprietary name, Tascenso ODT, in their submission. This proprietary name is comprised of a single word with a suffix modifier that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. We assess the modifier, ODT, in Section 2.2.5 below.

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 25, 2021, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to Tascenso ODT at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred eighteen practitioners participated in DMEPA's prescription studies for Tascenso ODT. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. However, one inpatient study participant omitted the proposed modifier, one outpatient study participant misinterpreted ODT as "CDT", and one verbal study participant misinterpreted ODT as "OTD". We discuss the risk associated with omission and misinterpretation of the modifier in Section 2.2.5 below.

Appendix B contains the results from the prescription simulation studies.

[b] USAN stem search conducted on August 17, 2021.

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2.2.5 Safety Assessment of the Modifier, ODT

We assessed the proposed modifier, ODT, for appropriateness and for the risk of name confusion if the modifier is omitted/overlooked.

The proposed modifier, ODT, is currently utilized in the marketplace.[c] It is typically used to convey the meaning "orally disintegrating tablet" for products designed to disintegrate or dissolve rapidly on contact with saliva.[d] Provided the Office of Pharmaceutical Quality (OPQ) determines that the product meets the criteria for an orally disintegrating tablet, the modifier may help to communicate the orally disintegrating characteristic of the tablet.

We note, omission and oversight of modifiers is cited in literature as a common cause of medication errors.[e] Although we acknowledge modifiers may be omitted or overlooked (as seen in the August 23, 2021 FDA Prescription Simulation Study) when used, they can assist in differentiating products and may help to prevent potential product selection errors. The proposed modifier, ODT, may serve as a signal to health care practitioners that this product differs from the currently marketed fingolimod capsules and may reduce the potential for errors related to wrong technique of administration.

As described in Section, 2.2.4, the modifier, ODT, was misinterpreted as "CDT" and "OTD" in the August 23, 2021 FDA Prescription Simulation Study. We are unaware of any postmarket reports of medication errors documenting misinterpretation of ODT as another modifier. Also, on September 14, 2021, we searched MedicineNet[f] and Abbreviations.com[g], to determine if CDT or OTD are medical abbreviations that may increase the risk for proprietary name confusion or wrong drug medication errors. Our search did not identify any results that pose a risk of medication errors from these misinterpretations. Therefore, we are not concerned the modifier, ODT, will be misinterpreted as another modifier or medical abbreviation.

Additionally, we note that the "ODT" modifier is not being used to differentiate this product from a different product marketed under the root name "Tascenso" (e.g., a different dosage form of Tascenso). As such, if the "ODT" modifier is omitted or overlooked, the correct "Tascenso ODT" product would still likely be dispensed.

Therefore, we find the proposed modifier, ODT, is acceptable for use in this situation.

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[c] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

[d] Guidance for Industry: Orally Disintegrating Tablets. Food and Drug Administration. 2008. Available from http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070578.pdf.

[e] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

[f] MedicineNet medical abbreviation search conducted on September 14, 2021 at https://www.medicinenet.com/common_medical_abbreviations_and_terms/article.htm

[g] Abbreviations.com medical abbreviation search conducted on September 14, 2021 at https://www.abbreviations.com/

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[h] identified 208 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	4
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	187
Low similarity name pair: combined match percentage score ≤54%	17

2.2.8 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 208 names contained in Table 1 determined none of the names will pose a risk for confusion with Tascenso ODT as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Neurology 2 (DN 2). At that time we also requested additional information or concerns that could inform our review. On September 29, 2021, the Division of Neurology 2 (DN 2) stated no additional concerns with the proposed proprietary name, Tascenso ODT.

3 CONCLUSION

The proposed proprietary name, Tascenso ODT, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO HANDA NEUROSCIENCE, LLC

We have completed our review of the proposed proprietary name, Tascenso ODT, and have concluded that this name is acceptable.

[h] POCA search conducted on August 17, 2021 in version 4.4.

If any of the proposed product characteristics as stated in your submission, received on August 13, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [i]

[i] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[j]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[j] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Reference ID: 4866089

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

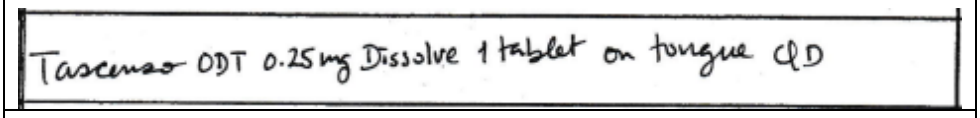
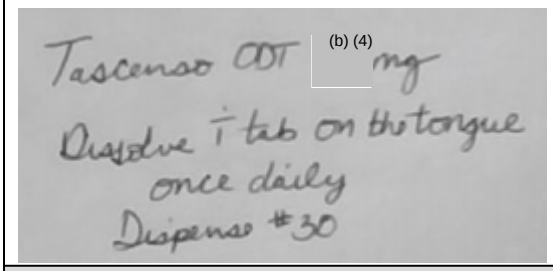
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Tascenso ODT Study (Conducted on August 23, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Tascenso ODT (b) (4) mg Dissolve 1 tablet on the tongue once daily. Dispense # 30
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Tascenso ODT	

FDA Prescription Simulation Responses (Aggregate Report)

As of Date 9/8/2021

262 People Received Study

118 People Responded

Study Name: Tascenso ODT

Total	28	35	25	30	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
TASCAMAS ODT	0	0	0	1	1
TASCE -- CAN'T READ	0	0	0	1	1
TASCEMAO ODT	0	0	0	1	1
TASCENSO	0	0	0	1	1
TASCENSO CDT	1	0	0	0	1

TASCENSO ODT	27	35	1	17	80
TASCENZO ODT	0	0	0	3	3
TASCEUSO ODT	0	0	0	2	2
TASCEUZO ODT	0	0	0	1	1
TASCUSO ODT	0	0	0	1	1
TASEMAO ODT	0	0	0	1	1
TASENCSO ODT	0	0	1	0	1
TASENSO ODT	0	0	5	0	5
TASENZO ODT	0	0	1	0	1
TAXCENSO ODT	0	0	0	1	1
TERSENSO ODT	0	0	1	0	1
TESANSO ODT	0	0	1	0	1
TESCENSO ODT	0	0	1	0	1
TESENSO ODT	0	0	1	0	1
TESSANSO ODT	0	0	1	0	1
TUSENSO ODT	0	0	4	0	4
TUSENZO ODT	0	0	1	0	1
TUSSENSO ODT	0	0	4	0	4
TUSSENSO OTD	0	0	1	0	1
TUSSENZO ODT	0	0	1	0	1
TUSSSENSO ODT	0	0	1	0	1

Reference ID: 4866089

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) (b) (4) **Usual Dose:** 1 tablet once daily	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Tascenso***	100	Root name for Tascenso ODT*** which is the subject of this review.
2.	Tascenso Odt***	78	Subject of this review.
3.	Caseins	74	Product is not a drug. It is a protein used in allergen extract tests.
4.	Quasense	70	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (T vs. Q). Phonetically, Tascenso ODT has more syllables than Quasense and the names sound different when spoken (tuh-SEN-soh vs. qua-sense). Additionally, there is no direct overlap in strength (0.25 mg (b) (4) vs. 0.03 mg/0.15 mg), and since Tascenso ODT is proposed to be available in multiple strengths, a strength must be provided on a prescription for it. Furthermore, the "ODT" modifier provides additional orthographic and phonetic differences if included.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Natesto	68
2.	Aptensio	66
3.	Asepso	66
4.	Fasenra	65
5.	(b) (4)***	64
6.	Katinko	62
7.	Tavneos***	62

No.	Name	POCA Score (%)
8.	Triesence	62
9.	Pizensy	60
10.	Senosol	60
11.	Tyvaso	60
12.	Kcentra	59
13.	Tessalon	59
14.	(b) (4)***	58
15.	(b) (4)***	58
16.	Trisenox	58
17.	Senna Soft	57
18.	Tagrisso	57
19.	Tarceva	57
20.	Tencon	57
21.	(b) (4)***	57
22.	Nucynta	56
23.	Tandem F	56
24.	Tecentriq	56
25.	Tis-U-Sol	56
26.	Trancot	56
27.	Trulance	56
28.	Sani-Clens	55
29.	Scenesse	55
30.	Tapentadol	55
31.	(b) (4)***	54

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	(b) (4)***	66	This name pair has sufficient orthographic and phonetic differences.
2.	Consensi	66	This name pair has sufficient orthographic and phonetic differences.
3.	Sufenta	66	This name pair has sufficient orthographic and phonetic differences.
4.	K-Vescent	65	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5.	Alecensa	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (T vs. A) and second letters (a vs. l), which gives the prefixes different shapes when scripted. Phonetically, the first syllables (tuh vs. a or ale) sound different when spoken. Further, the "ODT" modifier provides additional orthographic and phonetic differences if included.
6.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.
7.	Jatenzo	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, Jatenzo contains the cross-stroke letter 't' in the 3rd position, whereas Tascenso ODT does not contain any cross-stroke letters in the infix. Additionally, Jatenzo contains the optional downstroke letters 'J' and 'z', whereas Tascenso ODT does not contain any downstroke letters. These differences may give the names different shapes when scripted. Phonetically, the onset of the first two syllables (tuh-SEN vs. juh-TEN) sound different when spoken. Further, the "ODT" modifier provides additional orthographic and phonetic differences if included. Additionally, there is no direct overlap in strength (0.25 mg (b) (4) vs. 158 mg, 198 mg, and 237 mg), and since both products are supplied in multiple strengths a strength must be included on a

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			prescription. Furthermore, there is no direct overlap in frequency of administration (once daily vs. twice daily), which may provide additional differentiation if included.
8.	Tasigna	63	This name pair has sufficient orthographic and phonetic differences. Orthographically, Tasigna contains the dotted letter 'i' in the 4th position and the downstroke letter 'g' in the 5th position, while Tascenso ODT does not contain any dotted or downstroke letters. These differences give the names different shapes when scripted. Phonetically, the ending of the second syllables (SEN vs. sig), and the third syllables (soh vs. na) sound different when spoken. Additionally, both products are available with multiple strengths that do not directly overlap (0.25 mg (b) (4) vs. 50 mg, 150 mg, and 200 mg), thus, strength must be designated on a prescription. Furthermore, there is no direct overlap in frequency of administration (once daily vs. twice daily), which may provide additional differentiation if included.
9.	Masanti	62	This name pair has sufficient orthographic and phonetic differences.
10.	Acetasol	61	This name pair has sufficient orthographic and phonetic differences.
11.	Asceniv	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (T vs. A).

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, the first syllables (tuh vs. a) and third syllables (soh vs. iv) sound different when spoken. Furthermore, the "ODT" modifier provides additional orthographic and phonetic differences if included.
12.	Tussin Cf	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names differ in length (root names: 8 vs. 6 letters; names with modifiers: 11 vs. 8 letters). Additionally, Tussin contains the dotted letter 'i', whereas Tascenso does not contain any dotted letters, which give the names different shapes when scripted. Phonetically, Tascenso ODT has more syllables than Tussin CF. Additionally, the ending of the first syllables (tuh vs. tuss), and the onset of the second syllables (SEN vs. in) sound different when spoken. Additionally, there is no direct overlap in strength (0.25 mg (b) (4) vs. 20 mg-200 mg-10 mg per 10 mL or 10 mg-100 mg-5 mg per 5 mL), and since Tascenso ODT is proposed to be available in multiple strengths, a strength must be provided on a prescription for it. Furthermore, there is no direct overlap in dosage form (orally disintegrating tablet vs. solution) and frequency of administration (once daily vs. every 4 hours as needed), which may provide additional differentiation if included. Furthermore, the "ODT" modifier provides additional orthographic and phonetic differences if included.

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	Talzenna	58	This name pair has sufficient orthographic and phonetic differences. Orthographically, Talzenna contains the upstroke letter 'l' in the 3rd position and the optional downstroke letter 'z' in the 4th position, whereas the root name Tascenso does not contain any upstroke or downstroke letters, which give the names different shapes when scripted. Phonetically, the ending of the first syllables (tuh vs. Tal) and the third syllables (soh vs. ah) sound different when spoken. Furthermore, the "ODT" modifier provides additional orthographic and phonetic differences if included.
14.	Pentasa	56	This name pair has sufficient orthographic and phonetic differences.
15.	Tazicef	56	This name pair has sufficient orthographic and phonetic differences.
16.	Trinessa	56	This name pair has sufficient orthographic and phonetic differences.
17.	Lotensin	55	This name pair has sufficient orthographic and phonetic differences.
18.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences. (b) (4)

No.	**Proposed name:** Tascenso ODT **Established name:** fingolimod **Dosage form:** orally disintegrating tablet **Strength(s):** 0.25 mg (b) (4) **Usual Dose:** 1 tablet once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			(b) (4)

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Nystavescent	53
2.	Acetone	52
3.	Betaseron	52
4.	Metacresol	51
5.	1-Octacosanol	50
6.	Anestacon	50
7.	Isocetane	50
8.	V-Tann Suspension	50
9.	Soap Sensations	49
10.	Ascot	48
11.	Sutan Suspension	48
12.	Typhim Vi	48
13.	Stay Clean	47
14.	Clascoterone	44

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	Antatens	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Prascend	66	Veterinary product.
3.	T-Tussin Pe	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Tussend	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Tussin Pe	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	(b) (4) ***	63	Proposed proprietary name for BLA 208751 found unacceptable by DMEPA (OSE# 2016-8522346-1) approved under the proprietary name Fiasp, Fiasp Flextouch, and Fiasp Penfill.
7.	(b) (4) ***	62	Proposed proprietary name for ANDA 091193 was found conditionally acceptable by DMEPA (OSE # 2012-222 dated June 13, 2012). However, ANDA 091193 received a Complete Response (CR) action April 25, 2013 and October 3, 2014. Subsequently, ANDA 091193 was approved on May 3, 2016 under the established name 'baclofen', under which the product is currently marketed.
8.	Diatensec	61	International product formerly marketed in the United Kingdom.
9.	Tannate 12D S	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	Talacen	60	Brand discontinued with no generic equivalents available. NDA 018458 withdrawn FR effective 08/19/2013.
11.	Tannate 12 S	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Tannic-12 S	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Testro	60	Name identified in RxNorm database. Testro is a root name for a product line that is deactivated and no generic equivalents are available.
14.	Tusso Df	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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No.	Name	POCA Score (%)	Failure preventions
15.	Atensine	59	International product formerly marketed in the United Kingdom and Ireland.
16.	(b) (4) ***	59	(b) (4)
17.	(b) (4) ***	59	
18.	Tussin V	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Clinsol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Metatensin	58	Name identified in RxNorm database. Metatensin is a root name for a product line that is deactivated and no generic equivalents are available.
21.	Metatensin #2	58	Brand discontinued with no generic equivalents available. NDA 012972 withdrawn FR effective 06/04/2004.
22.	Metatensin #4	58	Brand discontinued with no generic equivalents available. NDA 012972 withdrawn FR effective 06/04/2004.
23.	(b) (4) ***	58	(b) (4)
24.	Tetmosol	58	International product marketed in India, Brazil, and South Africa; and formerly marketed in Mexico, Singapore, Australia, the United Kingdom, and Ireland.
25.	Triotann-S	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
26.	Tussi-12D S	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
27.	Vancenase	58	Brand discontinued with no generic equivalents available. NDA 018521 withdrawn FR effective 06/04/2004.

No.	Name	POCA Score (%)	Failure preventions
28.	Vetasan	58	Veterinary product.
29.	Tadenan	57	International product marketed in China, Thailand, France, and Ukraine; and formerly marketed in multiple countries.
30.	Teslascan	57	Brand discontinued with no generic equivalents available. NDA 020652 withdrawn FR effective 11/26/1997.
31.	Tusana D	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
32.	Canesten	56	International product marketed and formerly marketed in multiple countries.
33.	Cea Scan	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Cenfol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Ketaset	56	Veterinary product.
36.	Lidosense	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
37.	Tegison	56	Brand discontinued with no generic equivalents available. NDA 019369 withdrawn FR effective 09/10/2003.
38.	Tekamlo	56	Brand discontinued with no generic equivalents available. NDA 022545 withdrawn FR effective 07/21/2017.
39.	Tisept	56	International product marketed in the United Kingdom and Singapore.
40.	Tolinase	56	Brand discontinued with no generic equivalents available. NDA 015500 withdrawn FR effective 06/18/2009.
41.	(b) (4) ***	56	Proposed proprietary name for IND 121211 found unacceptable by DMEPA (OSE# 2017-13620885). NDA 210861 and NDA 211710 approved under the proprietary name Vitrakvi.
42.	Trasicor	56	Brand discontinued with no generic equivalents available. NDA 018166 withdrawn FR effective 09/29/1995.
43.	Travenol	56	Product is not a drug. It is drug manufacturer in the UK.
44.	Tuss Ax	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
45.	Beta-Escin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	Oftasceine	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Pentasol	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
48.	Tissue Goo	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Tussgen	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
50.	Tussiden C	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
51.	Tussinate	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
52.	Osteoscan	50	Brand discontinued with no generic equivalents available. NDA 017454 withdrawn FR effective 05/29/2002.
53.	1-Tetracosanol	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[k].

No.	Name	POCA Score (%)
1.	Bavencio	62
2.	Bosentan	62
3.	Dytan-Cs	62
4.	Cesamet	61
5.	Patanase	61
6.	Antacid Ds	60
7.	Besponsa	60

[k] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
8.	(b) (4)***	60
9.	Citanest	60
10.	(b) (4)***	60
11.	Selenos	60
12.	Sutent	60
13.	Atacand	58
14.	Cerinta	58
15.	Dasetta 1/35	58
16.	Dasetta 7/7/7	58
17.	Nafrinse	58
18.	Nasex	58
19.	Nasosol	58
20.	Paracets	58
21.	Patanol	58
22.	(b) (4)***	58
23.	Qutenza	58
24.	Sancuso	58
25.	Saxenda	58
26.	(b) (4)***	57
27.	Betnesol	57
28.	Butrans	57
29.	Caseinate	57
30.	Cestex	57
31.	Vyvanse	57
32.	60 Second	56
33.	Anasept	56
34.	Asendin	56
35.	Atuss Ex	56
36.	Betavent	56
37.	(b) (4)***	56
38.	Calan Sr	56
39.	Cetafen	56
40.	Cophene No. 2	56
41.	Dalvance	56
42.	Desonate	56
43.	Ditate-Ds	56
44.	Ed-In-Sol	56
45.	Hetacin-K	56
46.	Nasatuss	56
47.	Nasin Nasal	56
48.	Nasonex	56
49.	Nasopen Pe	56
50.	Nasopen-Ch	56

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No.	Name	POCA Score (%)
51.	Nasotuss	56
52.	Panscol	56
53.	Pentids '200'	56
54.	Pentids '250'	56
55.	Pentids '400'	56
56.	Pentids '800'	56
57.	Placebo	56
58.	Prosed Ds	56
59.	Protein S	56
60.	Proteins	56
61.	Pse Sinus	56
62.	Psorent	56
63.	Sea Soft	56
64.	Senna S	56
65.	Serenus	56
66.	Staycept	56
67.	Stendra	56
68.	(b) (4) ***	56
69.	Vasaten	56
70.	Xoten-C	56
71.	Actacin	55
72.	Betalin S	55
73.	(b) (4) ***	55
74.	Datscan	55
75.	Fer-In-Sol	55
76.	Mucins	55
77.	Natacyn	55
78.	Q-Tussin Pe	55
79.	Saleto	55
80.	Saleto-200	55
81.	Saleto-400	55
82.	Saleto-600	55
83.	Saleto-800	55
84.	Sansac	55
85.	Saphnelo	55
86.	Senexon	55
87.	Sevenfact	55
88.	Sustanon	55

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	March 19, 2021
Application Type and Number:	NDA 214962
Product Name and Strength:	(b) (4) (fingolimod) orally disintegrating tablets, 0.25 mg (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Handa Neuroscience, LLC (Handa)
PNR ID #:	2020-1044427074
DMEPA Safety Evaluator:	Justine Kalonia, PharmD
DMEPA Acting Team Leader:	Celeste Karpow, PharmD, MPH
DMEPA Director:	Danielle Harris, PharmD

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